



October 20, 2010

RE: Supply of UNITAID-Financed Pediatric and/or Adult Second-Line Antiretrovirals for period of March 2011 - February 2012

The Clinton Health Access Initiative (“CHAI”); formerly the Clinton HIV/AIDS Initiative, a division of the William J. Clinton Foundation; is collaborating with UNITAID, an international drug purchase facility hosted by the World Health Organization (“WHO”), to increase the affordability of critical pediatric and second-line antiretrovirals (“ARVs”) for national HIV/AIDS treatment programs. UNITAID has given a “green light” for the extension of the Pediatric HIV/AIDS project through December 31, 2011 of US\$ 81.1 million, which will be considered by the UNITAID Board in November 2010, and approved US\$41.5 million ceiling for the Second Line HIV/AIDS project through December 2011, and is expected to fund the purchase of specific pediatric ARVs for up to 40 developing countries through 2011 and of specific second-line ARVs for up to 25 developing countries through 2011<sup>1</sup>. The ARV products expected to be procured through both these UNITAID-funded projects in 2011 would have a total value of up to US\$90 million (based on current market prices).

The process initiated by this letter will determine the selection of Manufacturers, pricing and allocation of volumes for pediatric ARV and adult second-line ARV orders from **March 1, 2011 through February 28, 2012**. Another process will be conducted next year for supply and pricing of orders for the twelve months following this period.

This letter serves to inform manufacturers of the processes, terms and conditions of the selection of Manufacturers for the UNITAID-funded pediatric and second-line ARVs. It is requested that interested manufacturers respond to this letter with an expression of interest (“EOI”) for each of the two projects, Pediatric and Second-Line. EOIs must be received **by no later than November 12, 2010**. As explained more fully in Sections 3 and 5 below, EOIs for each project must include bid notifications for each product that the company proposes to supply. Bid notifications can take either of two forms:

(1) Manufacturers may make a traditional price proposal. Such a traditional price proposal should specify product pricing, associated terms and conditions of sale, regulatory status of product, preparedness to supply and willingness to abide by the conditions of the project; or

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<sup>1</sup> The UNITAID programs have been designed from the beginning to be catalytic, time-limited programs that produce lasting changes in market dynamics. Consistent with this, UNITAID has begun phasing out funding for the second-line Project at the end of 2009 and will begin phasing out for the pediatric Project at the end of 2010. Other long-term funders, such as PEPFAR and the Global Fund, will assume responsibility for continued funding of the relevant commodities in UNITAID beneficiary countries. As such, in 2011, while the maximum number of countries in the programs is 40 for pediatrics and 25 for second-line, not all countries are guaranteed to place orders through the UNITAID program.

(2) Manufacturers may indicate their willingness to engage in “cost-plus” pricing negotiations with CHAI for a limited set of products. These negotiations can be based on product cost information provided either in response to a CHAI template or, alternatively, in the form of audited costs provided by an independent accounting firm. CHAI templates for cost-plus disclosure are being sent as separate attachments to this letter (see Section C of Schedules 1 and 2, respectively, and attached excel files). Manufacturers willing to engage in confidential cost-plus pricing negotiations must make this intention known in writing **by November 5, 2010** and provide requested cost information in the EOI for the relevant project(s) **by November 12, 2010**. **CHAI will only engage in cost-plus negotiations on a sub-set of formulations described below;** for other formulations, manufacturers can only make a traditional price proposal.

**Please note that CHAI will continue with reduced cost-plus requirements introduced last year, and that less data will be required than in selection processes prior to that.** Schedule 1, section D and Schedule 2, section D provides the set of pediatric and second-line products, respectively, for which cost-plus negotiations will take place, and describes the reduced data requirements. Manufacturers may elect to engage in cost-plus price negotiations for any or all of the product categories listed in Schedule 1, section D and Schedule 2, section D. Should a Manufacturer elect to engage in cost-plus price negotiations for a category, product cost information must be provided for all products in that category.

Following submission, CHAI will proceed through a selection process that is more fully detailed in Section 3 below. CHAI will confirm the eligibility of Manufacturers. Thereafter, based on several factors listed in Section 3 (including but not limited to price, regulatory status and willingness to abide by the conditions of the project), CHAI will select a primary and secondary Manufacturer(s) for each product, as well as Manufacturers to be included in a residual Manufacturer pool. Selection of eligible Manufacturers and negotiation of pricing agreements will be completed on a timeline to permit orders to be placed beginning in March 2010.

The sections below provide additional information on the roles and responsibilities of UNITAID and CHAI; the process for the selection of Manufacturers and for the procurement of products; and instructions for how to respond to this letter and participate in the projects.

Only manufacturers are invited to submit proposals and only manufacturers selected as an outcome of this process will be privileged to participate in this project.

## **1. Roles and Responsibilities**

### **1.1 UNITAID**

UNITAID ([www.unitaid.eu](http://www.unitaid.eu)) aims to increase access to treatment for HIV/AIDS, malaria and tuberculosis for people in developing countries by lowering the price of high-quality drugs and diagnostics and accelerating the pace at which they are made available to patients in need. UNITAID uses predictable and additional funding to help generate steady demand for products. Financed mainly by a solidarity contribution on airline tickets and supplemented with funds from Brazil, Chile, France, Norway, the United Kingdom and other donors, UNITAID expects to raise \$350 million annually by 2010. Governed by a board including donors, representatives of developing countries, representatives of nongovernmental organizations, and the World Health Organization (“WHO”), as its host and trustee, UNITAID is focusing its resources initially on “niche” areas for which the supply of key products remains limited and prices remain high, including pediatric and second-line ARVs.

UNITAID funds will be used pursuant to WHO procurement principles, including best value for money, international competition and compliance with international quality standards.

UNITAID will be responsible for the consistent and timely provision of funding to enable the purchase and delivery of the specified pediatric and second-line ARVs for beneficiary countries, within budgets approved by the UNITAID board. (The beneficiary countries being supplied with UNITAID-funded products under these projects are specified in Section B of Schedules 1 and 2.) UNITAID has previously established in writing with beneficiary governments UNITAID's role, the role of CHAI and the responsibilities and undertakings of the governments, for these projects. UNITAID will also engage in ongoing review of the financial and technical progress of the projects and evaluate the performance of partners.

### 1.2 Clinton Health Access Initiative (CHAI)

Established in 2002 by President Clinton as the Clinton HIV/AIDS Initiative<sup>2</sup>, CHAI was created to support the efforts of national governments to expand HIV/AIDS care and treatment. Today, CHAI supports programs, in partnership with governments, in more than 35 countries in Africa, Asia, Latin America and the Caribbean. CHAI has signed agreements with more than a dozen manufacturers to lower the prices of pharmaceuticals and diagnostics used to treat HIV/AIDS.

With regard to cost-plus negotiation, CHAI has made its assistance in reducing production costs available since 2003 to manufacturers willing to share cost information and willing to price products on a cost-plus basis. With such manufacturers, CHAI works to model costs, then to identify and pursue opportunities for cost reductions arising from more predictable and larger volumes of demand. CHAI is committed to ensuring a sustainable business model for partner Manufacturers and therefore seeks to agree to cost and pricing models that incorporate costs of labor, materials, overhead and capital, plus a margin that affords the manufacturer a viable return (“cost-plus”). CHAI maintains an ongoing commitment to providing impartial cost reduction assistance to all Manufacturers. Cost information provided to CHAI also enables CHAI to gain a greater insight into price stability and availability of key raw materials, intermediates, and API, and thereby enabling CHAI to plan appropriately and provide counsel to governments on any anticipated problematic supply situations. Separately from the UNITAID Projects, CHAI works further up in the supply chain with Manufacturers of raw materials, intermediates, and API to reduce costs- and risks-of-production and address price volatility, thereby ensuring stable, reliable supply at affordable prices. These efforts benefit drug formulation manufacturers. The information collected through cost-plus negotiations helps inform where and how CHAI works to ensure a healthy marketplace of these key inputs into drug formulation production.

Since 2009, CHAI began engaging in cost-plus negotiations on a sub-set of formulations. CHAI has reduced the cost-plus requirements, and less data is required for each product than in past selection processes. Schedules 1 section D and Schedule 2, section D, describe the set of pediatric and second-line formulations, respectively, for which manufacturers can elect to engage in cost-plus negotiations. Schedule 9 describes the data requirements. Manufacturers may elect to engage in cost-plus price negotiations for any or all of the product categories listed. Should a Manufacturer elect to engage in cost-plus price negotiations for a category, product cost information must be provided for all products in that category.

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<sup>2</sup> As of January 1, 2010, the Clinton HIV/AIDS Initiative became a separate nonprofit organization called the Clinton Health Access Initiative (CHAI).

In addition, due to availability concerns and low volumes projected for 2011, CHAI will combine volumes for all of the didanosine (ddI) enteric coated formulations (i.e., 125mg, 200mg, 250mg and 400mg) together across both the UNITAID Pediatrics Project and Second-Line Project for the purposes of manufacturer selection. CHAI will choose up to two (2) manufacturers (a primary and a secondary) to supply all ddI enteric coated formulations. Manufacturers who only produce a subset of these formulations will be considered and are invited to respond to this letter. Similarly, CHAI will combine volumes for all of the ddI buffered formulations available under the Pediatric Project (i.e., 25mg, 50mg and 100mg) for the purposes of manufacturer selection and will select up to two (2) manufacturers (a primary and a secondary) to supply these formulations to the Pediatrics Project.

As part of the Pediatric and Second-Line Projects, CHAI, representing UNITAID, will undertake negotiations with manufacturers and oversee the procurement of products. As an outcome of the selection process, the Procurement Agent, on behalf of CHAI and UNITAID will place Purchase Orders with manufacturers based upon legally binding “Master Supply Agreements” (MSAs). A precondition for selection is the Manufacturer’s willingness to sign MSAs with CHAI. Under the terms of such agreements, the selected Manufacturer(s) will undertake to supply the products at the agreed prices in the quantities ordered upon placement of purchase orders by the Procurement Agent. The prices in these agreements will represent ceiling prices for the duration of the Master Supply Agreements (i.e., through February 2012).

In the selection process, CHAI will apply appropriate strategies to enable the development of a healthy market that favors competition and sustainability, with reduction in prices. When feasible, the supply of any single product will be shared by more than one Manufacturer to sustain competition and minimize risks associated with supply shortages and over-dependence on a single or limited number of Manufacturers. Other objectives are to engage with industry to stimulate an increase in the availability of relevant drugs of assured quality and in the number of new Manufacturers and an expansion of the registration of products (or waivers thereof) with the regulatory authorities of the beneficiary countries.

Under the terms of Memoranda of Understanding (“MoU”) between CHAI and beneficiary governments, CHAI will also be responsible for helping governments access products covered by the UNITAID projects – with activities including protocol review and guidance, product quantification, and support to national drug regulatory authorities for timely registration of products. CHAI will also be responsible for reporting to UNITAID on the progress of the projects, the performance of Manufacturers, and achievement of key objectives.

### 1.3 Procurement Agents

A competitively selected procurement agent, contracted by CHAI and operating under terms agreed with UNITAID, will be responsible for purchasing, freight forwarding and quality control. In particular, the procurement agent will place orders for products from Manufacturers and at [maximum ceiling] prices specified by the outcome of the processes set forth in this letter. The agent will arrange with each specified Manufacturer for the ongoing supply and transportation of products. The agent will then issue purchase orders, based on product quantifications completed in close collaboration with beneficiary governments. For purchased products, the agent will be responsible for contracting for quality control services, including pre-shipment inspection and random batch testing. The agent will be responsible for ensuring product registration or waiver thereof prior to placing orders, port clearance and transportation to central medical stores

(consistent with MoU signed between CHAI and beneficiary countries, which will typically commit the beneficiary countries to waiving import duties and taking responsibility for transportation of products to treatment sites). Finally, the agent will be responsible for timely payment to Manufacturers following the delivery of products according to the terms of awarded contracts.

The procurement agent for the purchase of products under this letter for both Pediatric and Second-Line Projects is IDA Foundation of Amsterdam, The Netherlands.

#### 1.4 Manufacturers

Only manufacturers who duly submit an expression of interest in response to this letter and who meet the mandatory requirements listed in Schedule 4 will be considered eligible for participation in the selection process.

Manufacturers selected by the outcome of the process set forth in this letter will be responsible for the following: manufacture of high-quality products; submission of dossiers for the registration of these products with the national drug regulatory authorities of the beneficiary countries; compliance with the applicable quality assurance standards and quality control procedures; delivery of these products at agreed prices<sup>3</sup> for UNITAID-financed volumes to the beneficiary countries and to other purchasers on behalf of national treatment programs in other low and middle income countries as may be requested by UNITAID or CHAI, including those countries participating in CHAI's Procurement Consortium ("Consortium") (see Schedule 3); timely delivery of products consistent with ongoing purchase orders; adherence to other applicable terms and conditions of the projects. Further information on conditions of eligibility of and participation by Manufacturers in the UNITAID-funded Second-Line and Pediatric Projects is described below in Section 3.

Additionally, the selection of Manufacturers will be conditional to sign MSAs with CHAI for long term supply of agreed products at prices not exceeding the quoted prices.

#### 1.5 Beneficiary Governments

Consistent with agreements signed with UNITAID, as well as MoUs signed with CHAI, beneficiary governments will be responsible for the receipt and effective use of products covered in these projects. This will typically include responsibility for product registration by national drug regulatory authorities; quantification and order scheduling; receipt, port clearance and central warehousing; and transportation to treatment centers. This will also include accountability for rational use of products, including provision to patients consistent with international treatment guidelines, and effective supply chain management and monitoring. Beneficiaries will be responsible for the provision of documents confirming product delivery and of agreed data for reporting of the consumption and use of products. They will also be responsible for paying (or facilitating the waiver of) duties and local costs for products covered by the project; to supply these

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<sup>3</sup> As noted above, prices for the products secured via this process will represent ceiling prices for the duration of the later of February 28, 2012 or the term of the Master Supply Agreements. Exceptionally, should a significant and sustained change in circumstances create a need for price adjustment, such adjustment shall be subject to the advance written approval of UNITAID. Such a request must be submitted to UNITAID, through CHAI, at least one month prior to the requested effective date, together with documentary proof of the circumstances that are claimed to warrant a price adjustment. While the request is under consideration by UNITAID and CHAI, the Manufacturer is expected to continue to supply the product without interruption at the originally agreed upon price. No retroactive price increases will be permitted for purchase orders already issued to and accepted by the Manufacturer.

products free of charge; to distribute them securely to avoid diversion; and to comply with international and national law. For lists of beneficiary countries of the UNITAID-funded Pediatric and Second-Line HIV/AIDS Projects, see Section B of Schedules 1 and 2, respectively.

## **2. Description of the Projects**

For each pediatric and second-line ARV treatment to be procured with UNITAID financing, a pool of Manufacturers –where more than one qualified manufacturer exists, a primary and secondary Manufacturer – will be selected through the three-phase process described more fully in Section 3 below. For certain products, three Manufacturers – a primary and two secondary Manufacturers – will be selected. For certain other products, only one Manufacturer will be selected. The Procurement Agent will issue purchase orders and pay participating Manufacturers at agreed prices for all volumes financed by UNITAID, consistent with the outcome of this process.

The pediatric and second-line products covered by this process are specified in Section A of Schedules 1 and 2, respectively. Detailed packaging, labeling and insert requirements will be specified in ongoing purchase orders. CHAI will procure products indicated for use in pediatric and adult second-line HIV/AIDS care and treatment, consistent with international guidelines, as revised by WHO in 2009, and national protocols. For pediatric and second-line ARVs, the indicative volumes of UNITAID-financed purchases for the project as a whole are also included in Section A of Schedules 1 and 2, respectively.

The maximum of 40 countries for which procurement of pediatric ARVs will be conducted with UNITAID financing as part of this project are specified in Schedule 1, Section B. The maximum of 25 countries for which procurement of second-line ARVs will be conducted with UNITAID financing as part of this project are specified in Schedule 2, Section B. The outcome of the process set forth in this letter will determine prices and Manufacturers **for medicines ordered during the twelve month period beginning March 1, 2011**. An additional process will be conducted next year for supply and pricing for the following twelve-month period.

Although UNITAID will finance purchases only for the countries specified in Section B of Schedules 1 and 2, respectively, it intends to extend prices agreed to other low and middle income countries as UNITAID may request, including the members of the CHAI Consortium. The current members of the Consortium are specified in Schedule 3. (The Consortium is comprised of countries which have signed an agreement with CHAI committing to follow standard procurement procedures, work to improve procurement practices over time, and access negotiated prices consistent with applicable terms and conditions. The list would be updated periodically.)

## **3. Manufacturer Selection Process**

This section outlines the mandatory eligibility criteria for participation in the Manufacturer selection process, the procedural steps of the process and the assessment criteria for Manufacturer selection and volume allocation.

In order to be considered eligible to participate in the selection process, Manufacturers are required to meet certain mandatory requirements, which are set out in Schedule 4 (see Section 3.1.2 below), which is required to be signed and submitted with the Manufacturer's EOI.

For both the Pediatric and Second-Line Projects, a three-phase process will be followed to select a pool of Manufacturers per product for orders placed **from March 1, 2011 through February 28, 2012**. The first phase, described below in Section 3.1, offers an opportunity for eligible manufacturers to make an initial proposal, which will determine a primary Manufacturer per product. The second phase, described below in Section 3.2, offers an opportunity for a second proposal to be made, after which a secondary Manufacturer (or Manufacturers) will be determined. The third phase, described below in Section 3.3, provides for the selection of the residual pool of Manufacturers per product for volumes to be supplied. The Manufacturers selected as the primary, secondary and to the pool of tertiary Manufacturers could be allocated a proportion of volumes for the pediatric and second line projects in accordance with the procedures described below in Section 4.

For products available from only one Manufacturer, CHAI will engage in price negotiations with that Manufacturer irrespective of whether the Manufacturer has submitted a traditional price proposal or an indication of willingness to engage in the “cost plus” process. These negotiations will be aimed at achieving the best possible price based on anticipated volumes. (For all products for which there are multiple Manufacturers, the process detailed in Section 3.1 below will be followed.)

CHAI and UNITAID reserve the right to conduct further negotiations and/or tenders in 2011 for the supply of formulations (including formulations not listed in Schedules 1 and 2) for which there is currently no eligible Manufacturer, and/or for formulations currently available from only one Manufacturer once one or more additional Manufacturers become eligible. In particular, regarding formulations for which there is currently no eligible Manufacturer, CHAI and UNITAID may elect to negotiate directly with the first manufacturer to develop an eligible product and/or to conduct a tender once two or more manufacturers have become eligible.

### 3.1 Phase I

#### 3.1.1 Expressions of interest

Manufacturers' EOIs must include bid notifications for each product. Bid notifications may take either of two forms: (1) a traditional price proposal, including associated terms and conditions or (2) an indication of willingness to engage in cost-plus pricing negotiations with CHAI, for each of the categories of products listed in Schedule 9, using as a basis either cost information provided using a CHAI template or as provided by an independent accounting firm.

#### 3.1.2 Screening for eligibility

Consideration of traditional price proposals and/or cost-plus negotiations will depend on each interested Manufacturer meeting the mandatory conditions necessary to participate in these projects as detailed in Schedule 4. These include the regulatory status of the product; compliance with UNITAID's quality assurance standards and CHAI's quality control procedures; willingness to extend prices to additional countries which are not UNITAID beneficiaries for the Pediatric or Second-Line Projects, including, at a minimum, members of the CHAI Consortium; and adherence to other terms and conditions associated with the supply of the products. Schedule 4 must be signed and submitted with the Manufacturer's Expression of Interest in response to this letter, together with associated documentation (see Section 5 below). Proposers not complying with these mandatory criteria may be eliminated from the process.

For purposes of emphasis, your attention is especially directed to the requirements of Schedules 6 and 7 relating to, respectively, quality assurance standards and quality control procedures for the products to be supplied.

With regard to quality assurance standards, only drugs meeting standards and specifications in conformity with UNITAID's quality assurance policy, as outlined in Schedule 6, are considered acceptable for procurement funded by UNITAID. Hence, all drugs procured for these projects are required to be in compliance with national regulatory standards and to be prequalified by WHO or other stringent national regulatory authority (see further definition in Schedule 6), which includes compliance with standards for good manufacturing practices ("GMP"). In the case of single or limited-source pharmaceuticals, (a) the drugs must be either prequalified by WHO or approved by a stringent regulatory authority **by November 12, 2010** or (b) in case there is only one or no equivalent product that meets this condition, an application for approval together with a complete dossier for the product must have been submitted to the WHO or another stringent regulatory authority **by November 12, 2010** and the product must be manufactured at a site that is compliant with WHO or stringent regulatory authority standards of GMP, provided that the Ministry of Health of the beneficiary country concurs that the products may be supplied on the basis of the conditions set out in (b).

Where a product falls into category (b), to be considered eligible for participation in the projects, Manufacturers should provide proof of having submitted an application for dossier assessment together with a complete product dossier to the WHO or other stringent regulatory authority and same having been accepted as complete by. Section 5 below sets out the documentary requirements for EOIs submitted for any product for which approval is pending from a stringent regulatory authority.

Furthermore, where a product falls into category (b), it must be reviewed for quality, efficacy and safety and receive an interim recommendation for procurement for a period not exceeding 12 months, based on advice provided by the Expert Review Panel (ERP) as convened by UNITAID or The Global Fund, before procurement can begin. If the product does not meet the applicable quality criteria, the product will not be supplied with UNITAID funds.

With regard to quality control requirements, Manufacturers must also agree to adhere to the obligations set out in Schedule 7, including testing and pre-shipment inspections to be performed by a testing agency specified by CHAI and the related measures to be undertaken by Manufacturers to facilitate such inspections.

### *3.1.3 Forms of bids; traditional price proposals and cost-plus pricing negotiations*

Manufacturers willing to engage in cost-plus negotiations with CHAI must indicate their intention in writing, **by November 5, 2010** and for which of the pediatric and second-line product categories listed in Schedule 1, section D and Schedule 2, section D, respectively. For the purposes of disclosing confidential cost information, mutual non-disclosure protection with interested Manufacturers is available in the form of the agreement set forth in Schedule 8. Manufacturers will provide by a completed cost template for the presentation of the Manufacturer's production costs for each relevant product, along with the other information requested in this letter. (See Section C of Schedules 1 and 2, respectively and attached excel files.) Alternatively, Manufacturers can return an overview of product costs for each relevant product completed by an independent accounting firm.

For each product, the best price submitted in the form of a traditional price proposal from an eligible Manufacturer, but not the source of this price, will be disclosed to all Manufacturers that have revealed production cost information for that product as part of cost-plus negotiations. Subsequently, beginning the week of **December 6, 2010**, CHAI will meet with these Manufacturers to review and discuss their production costs, agree on and model opportunities for cost reductions, and negotiate cost-plus prices. CHAI will sequence and conduct discussions with all such Manufacturers in an impartial manner seeking to achieve the best possible prices regardless of the status of discussions with other Manufacturers. The final cost-plus prices reached in discussions with each such Manufacturer shall be treated as that Manufacturer's first proposal.

Requests for additional information, including further detail on the process of providing cost information or engaging in cost-plus negotiations, should be submitted in writing and forwarded to Neeraj Mohan (mneeraj@clintonhealthaccess.org) referencing: CHAI: Manufacturer Letter for UNITAID-financed Pediatric and/or Second-Line Antiretrovirals in the subject header. Any request for additional information, and the answers of CHAI thereto, will be made available to all parties who are receiving this letter.

#### 3.1.4 *Selection of primary Manufacturer*

The first proposals from each eligible Manufacturer, obtained either as a traditional price proposal or following cost-plus negotiations, will be reviewed and compared. For any given product, in selecting the primary Manufacturer, CHAI will take in to consideration the Manufacturer with the best price and other factors, including but not limited to lead times and the Manufacturers' ability to supply to the countries in question (as determined by national registrations and its ability to meet the volume required). A supplement to Request for Proposal dated November 9, 2009 entitled "Inclusion of Non-Price Factors in Supplier Selection Criteria for UNITAID-financed Pediatric and Adult Second-Line Antiretrovirals (ARVs)" attached to this letter describes the selection criteria. Such Manufacturer will be designated as the **primary Manufacturer** for orders of that product under the project, provided that the Manufacturer is prepared to extend the proposed price to other low and middle income countries as may be requested by UNITAID or CHAI, including members of the CHAI Consortium as set forth in Schedule 3. The primary Manufacturer for the pediatrics and second-line projects will be allocated a percentage proportion of volume according to the criteria set forth in Section 4 below.

For certain products for which the forecasted volume for the product in 2011 is less than four (4) times the size of the minimum production batch, CHAI may elect to select only one Manufacturer and the selection process will terminate at Phase I. Please refer to Schedule 1 Section B for a list of potential products that may fall in this category.

### 3.2 *Phase II*

#### 3.2.1 *Request for second proposals*

After selection of the primary Manufacturer, the price offered by that Manufacturer will be set as a "reference price." A written communication will then be sent to all other eligible Manufacturers notifying them of this "reference price" and inviting them to submit a second proposal for each product's remaining volume (i.e. 30-50%) being financed by UNITAID. Manufacturer for the Pediatric and Second Line projects will be allocated a percentage proportion of volume according to the criteria set forth in Section 4 below.

### 3.2.2 Submission of second proposals

These second proposals will be submitted in writing to CHAI and then reviewed simultaneously according to standard practice for tenders. An eligible Manufacturer which submitted a first proposal but which does not submit a second proposal will be evaluated based on the first proposal submitted, unless that Manufacturer explicitly indicates that it no longer wishes to participate in the projects.

### 3.2.3 Screening for eligibility

The eligibility criteria will be the same as in Phase I (described in section 3.1.2 above) except the applicable dates for approval by an SRA or submission for approval by an SRA, if applicable, as described below.

In the case of single or limited-source pharmaceuticals, (a) the drugs must be either prequalified by WHO or approved by a stringent regulatory authority **by January 28, 2011** or (b) in case there is only one or no equivalent product that meets this condition, an application for approval together with a complete dossier for the product must have been submitted to the WHO or another stringent regulatory authority **by January 28, 2011** and the product must be manufactured at a site that is compliant with WHO or stringent regulatory authority standards of GMP, provided that the Ministry of Health of the beneficiary country concurs that the products may be supplied on the basis of the conditions set out in (b).

Where a product falls into category (b), to be considered eligible for participation in the projects, Manufacturers should provide proof of having submitted an application for dossier assessment together with a complete product dossier to the WHO or other stringent regulatory authority and same having been accepted as complete **by January 28, 2011**. Section 5 below sets out the documentary requirements for EOIs submitted for any product for which approval is pending from a stringent regulatory authority.

Furthermore, where a product falls into category (b), it must be assessed and recommended for procurement by the Expert Review Panel convened by UNITAID or the Global Fund before procurement can begin.

### 3.2.4 Selection of secondary Manufacturer

Second proposals will be reviewed and compared based on the same selection criteria as in Phase I (described in Section 3.1.4 above). Once all the second proposals have been reviewed, in selecting the secondary Manufacturer, CHAI will take into consideration the Manufacturer that proposes the best price for each product – even if it is lower than the reference price - and the - Manufacturers' ability to supply to the countries in question (as determined by national registration (or waiver thereof) and its ability to meet the volume required). Such Manufacturer will be designated as the **secondary Manufacturer** for orders of that product under the project, provided that it is prepared to sign a MSA capping the proposed price for a fixed duration and extend the proposed price to other low and middle income countries as may be requested by UNITAID or CHAI, including members of the Consortium as set forth in Schedule 3. The secondary Manufacturer(s) for the pediatrics and second-line projects will be allocated a percentage proportion of volume according to the criteria set forth in Section 4.

For certain products a primary and two co-secondary Manufacturers will be sought and selected. These products will be selected for co-secondary Manufacturer selection based on a variety of factors, including but not limited to the following factors:

- if forecasted volumes are significant, generally above \$1 million in annual value;
- if the value associated with the forecasted volumes are significant, generally above 100,000 packs/bottles;
- if there are a large enough number of countries projected to procure the products such that CHAI can allocate volumes to three Manufacturers without having necessarily to split volumes within any one country (due to complexities of supply chain management and provider education materials, CHAI tries to avoid splitting volumes between two or more Manufacturers for one product within one country);
- if more than two Manufacturers can offer a similarly competitive levels of pricing to the Projects;
- if volumes are projected to grow in subsequent years; and
- if a high number of Manufacturers are eligible to supply the product to the Projects.

Second-line ARV formulations that are likely to be split between a primary and two secondary Manufacturers are listed in Schedule 2, section B. The primary and co-secondary Manufacturers for the second-line project will be allocated a percentage proportion of volume according to the criteria set forth in Section 4.

### 3.3 Phase III

#### 3.3.1 Final determination of residual Manufacturer pool

In addition to the primary Manufacturer and secondary Manufacturer(s), selected through the process described above, eligible Manufacturers that submit a price in their second proposal which is at or below the reference price and above the price submitted by the secondary Manufacturer(s) may be selected to participate in the residual Manufacturer pool. This determination shall be applicable to the tender period of March 1, 2011 – February 28, 2012. Other than the primary and secondary Manufacturer(s), none of the Manufacturers included in the final pool will be guaranteed any UNITAID-financed volumes. However, these Manufacturers may receive volumes in cases where the primary or secondary Manufacturer(s) is unable to supply to a certain country as described in Section 4 below.

#### 3.3.2 Contractual Agreements and Example of Process

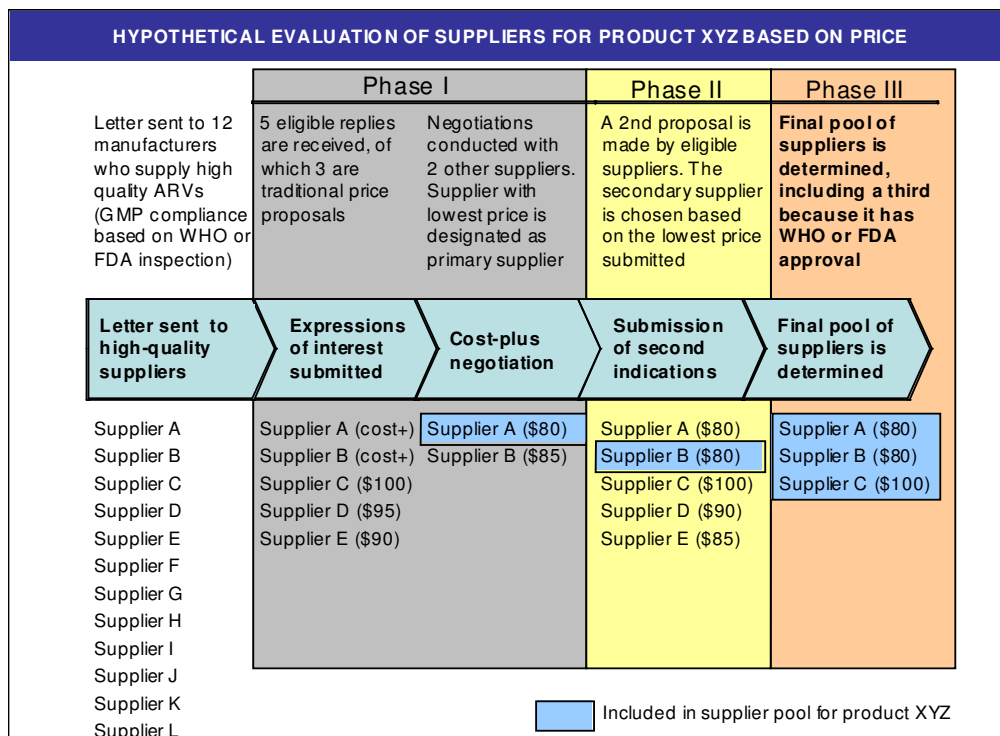
As a condition of selection, each Manufacturer will be required to enter into Master Supply Agreements with CHAI on behalf of UNITAID to commit to the agreed prices and terms on standard conditions consistent with applicable UNITAID requirements for a period not less than 12 months. In addition, each selected Manufacturer will be required to execute purchase orders placed by the selected Procurement Agents under the respective projects on standard conditions that are substantially the same as those set forth in Schedule 5.

Please Note: Any Primary or Secondary Manufacturer who has not signed a Master Supply Agreement covering 2011 will be required to do so if selected under Sections 3.1.4 and 3.2.4 above. CHAI will provide a form of Master Supply Agreement in the communication regarding selection of Primary and Secondary Manufacturers. Any Primary or Secondary Manufacturers who refuses or unreasonably delays the signing of the Master Supply Agreement will not be granted the volumes allocated to such Manufacturer according to Section 4 below

All proposals from Manufacturers and a report of the selection process will be provided by CHAI to UNITAID, subject to mutual non-disclosure agreements (see [Schedule 8](#)) between CHAI and Manufacturers.

CHAI reserves the right to use the registration information collected during the selection process for the purpose of increasing access to key products included in the program.

To summarize the process described above in this section, the process which will be used to select Manufacturers is schematically represented below, using a hypothetical example based solely on price. In this year's selection, other factors will be considered.



#### 4. Volume Allocation and Procurement

For products for which only a primary and secondary supplier are selected, once Manufacturer selection is concluded and a group of Manufacturers is established for each product, the primary Manufacturer will be offered a majority of volumes, but not more than 70% of total volumes for the product in question. The secondary Manufacturer will be offered the remainder of volumes not allocated to the primary Manufacturer but not less than 30%. For products for which a primary and two secondary Manufacturers are selected, the primary Manufacturer will be offered 40-60% of total volumes for the product in question, and the secondary Manufacturers will split the remaining 40-60% of volumes.

Other Manufacturers in the residual Manufacturer pool may be awarded volumes where neither the primary nor secondary Manufacturer(s) is able to meet delivery needs for a given beneficiary country. These volume allocations are subject to the respective Manufacturers' ability to supply to the country in question (as determined by national registration or waiver thereof) and the Manufacturer's ability to meet the packaging requirements and the delivery dates specified in the

purchase order, as well as relevant administrative factors such as avoidance of interruption of supply. Volume allocations are further subject to the signing of Master Supply Agreements as set forth in Section 3.3.2 above.

Section D of Schedules 1 and 2 shows historical order volumes by country for products in the UNITAID Pediatric and Second-Line Projects, respectively as well as products which may be allocated volumes between a primary and two secondary Manufacturers. These data are provided to help inform Manufacturers' decision-making about pricing and prioritization of dossier submissions for beneficiary country registrations. Manufacturers are advised to take their registration and regulatory status into account in gauging volume expectations.

Depending on the product, delivery will typically be required within eight to twelve weeks of acceptance of a purchase order. Payment will be made to manufacturers within 45 days of delivery provided that proof of delivery has been received by the Procurement Agent.

## 5. Required Information for Responses

Eligible Manufacturers that wish to supply to the Pediatric and/or Second-Line Projects must submit an Intention to bid to CHAI by **no later than November 12, 2010**, including the following information:

1. The technical specifications for each product that the company proposes to supply to the project. All products supplied to the UNITAID Pediatric and Second-Line projects as an outcome of this Tender must be manufactured according to the same specifications of the product proposed which that were pre-qualified or approved by the relevant stringent regulatory authority (or, where relevant, are set out in an application for approval to such authority).
2. For all products whose prequalification or approval application is pending before a stringent regulatory authority, the Manufacturer must submit the following: (a) proof of the submission of an application for approval together with a complete dossier by **November 12, 2010** in the form of a file number or confirmation letter from the appropriate regulatory authority; (b) a copy of the dossier submitted for approval, and (c) a copy of the site GMP certification by WHO or other from a stringent regulatory authority standards of GMP.
3. The registration status (or waiver) in all beneficiary countries for each product that the company proposes to supply.
4. For each product to be supplied, assurance of the manufacturer's capacity to supply up to 100% of the volumes listed in Section A of Schedules 1 and 2, or, alternatively, assurance of the magnitude of capacity available for that product in 2011.
5. A signed copy of Schedule 4 with the Manufacturer's commitment to the conditions set out therein.
6. For bid notifications following the 'traditional price proposal' form, proposal of prices and terms for the UNITAID-financed volumes associated with the beneficiary countries specified in Section A of Schedules 1 and 2. All prices should be quoted FCA Airport and it is preferred, but not mandatory, that prices be indicated in U.S. dollars. If quoted in a currency other than US dollars, prices must be accompanied by the exchange rate used..

7. Manufacturers willing to share detailed production cost information and engage in cost-plus price negotiations with CHAI on a confidential basis should notify CHAI in writing immediately and **no later than November 5, 2010**, with detailed cost information due **by November 12, 2010** (cost templates for both Pediatric and Second-Line products have been included as separate attachments to this letter). Provision of this information will be necessary before negotiations may begin. If requested, a mutual non-disclosure agreement in the form set forth in Schedule 8 may be executed.

Responses from Manufacturers headquartered in the United States, Canada or Europe should be sent to the attention of Alan Staple, Manager, Drug Access (astaple@clintonhealthaccess.org), at the Clinton Health Access Initiative, 383 Dorchester Avenue, Suite 400, Boston, MA 02127. All other Manufacturers should send their responses and inquiries to the attention of Neeraj Mohan, Director, Strategic Partnerships - Asia (mneeraj@clintonhealthaccess.org), at the Clinton Health Access Initiative, A-25, Hauz Khas, New Delhi – 110 016, India. Inquiries and other requests for information should be directed in accordance with the provisions set out in the last paragraph of Section 3.1.3 above.

Thank you for your commitment to making affordable HIV/AIDS treatment available to people in developing countries.

Best regards,

Inder Singh  
Director, Drug Access  
Clinton Health Access Initiative

cc: Jorge Bermudez, Executive Secretary, UNITAID

## SCHEDULES

1. Pediatric Project
  - List of UNITAID-financed pediatric ARVs and indicative order volumes for March 1, 2011 through February 28, 2012
  - List of pediatric ARVs likely to be sourced from two secondary Manufacturers
  - List of beneficiary countries
  - Instructions for template for cost-plus negotiation disclosure
  - Historical volumes for the UNITAID Pediatric Project
2. Second-Line Project
  - List of UNITAID-financed Second-Line ARVs and indicative order volumes for March 1, 2011 through February 28, 2012
  - List of second-line ARVs likely to be sourced from two secondary Manufacturers
  - List of Beneficiary Countries
  - Instructions for template for cost-plus negotiation disclosure
  - Historical volumes for the UNITAID Second-Line Project.
3. Members of the CHAI Procurement Consortium (as of April 2010)
4. Mandatory Conditions of Participant Manufacturers
5. Standard Terms and Conditions of Product Procurement Under UNITAID Second-Line Treatment Project and the UNITAID Pediatric Treatment Project
6. Summary of Applicable UNITAID Quality Assurance Standard for Drugs Procured in Pediatric and Second Line ARV Projects
7. Quality Control requirements
8. Form of Non-Disclosure Agreement
9. Description of Cost-Plus Procedure and Informational Requirement

# SCHEDULE 1

## PEDIATRIC PROJECT

### Table of Contents

- A. List of UNITAID-financed pediatric ARVs and indicative order volumes for March 1, 2011 through February 28, 2012
- B. List of Pediatric ARVs likely to be sourced from one Manufacturer
- C. List of beneficiary countries
- D. Instructions for template for cost-plus negotiation disclosure
- E. Historical volumes for the UNITAID Pediatric Project

### A. LIST OF UNITAID-FINANCED PEDIATRIC ARVS AND INDICATIVE ORDERS FOR MARCH 1, 2011 THROUGH FEBRUARY 28, 2012

<u>Product</u>	<u>Strength Per Unit</u>	<u>Pack Size</u>	<u>Indicative Order Volumes (March 1, 2011 – Feb 28, 2012)</u>
Abacavir	20mg / ml†	240ml	30,000
Abacavir	60mg	60s	12,000
Abacavir	300mg	60s	15,800
Abacavir (dispersible)	60mg		18,000
Didanosine*	25mg	60s	12,500
Didanosine*	50mg	60s	
Didanosine EC**	125mg	60s	36,200
Didanosine EC**	200mg	60s	
Didanosine EC**	250mg	60s	
Efavirenz	50mg	30s	100,000
Efavirenz	100mg	30s	20,000
Efavirenz	200mg	90s	30,000
Efavirenz	200mg - scored	90s	80,000
Lamivudine	50mg / 5ml†	240ml	120,000
Lamivudine	150mg	60s	20,000
Nevirapine	50mg / 5ml†	240ml	150,000
Nevirapine	200mg	60s	18,000
Nevirapine dispersible	50 mg		24,000
Stavudine	1mg / ml†	200ml	20,000
Stavudine	15mg	60s	4,000
Stavudine	20mg	60s	6,000
Stavudine	30mg	60s	500
Zidovudine	50mg / 5ml†	240ml	156,800
Zidovudine	100mg	100s	15,000
Zidovudine	300mg	60s	6,000
<b><i>Fixed-dose formulations</i></b>			

Abacavir/Lamivudine	60/30mg	60s	200,000
Lopinavir / Ritonavir	80+20mg / ml†	300ml	40,000
Lopinavir / Ritonavir	100/25mg	120s	58,000
Lopinavir / Ritonavir	200/50mg	120s	15,000
Stavudine/Lamivudine	6/30mg	60s	57,900
Stavudine/Lamivudine	12/60mg	60s	30,000
Stavudine/Lamivudine	30/150mg	60s	60,000
Stavudine/Lamivudine/Nevirapine	6/30/50mg	60s	301,100
Stavudine/Lamivudine/Nevirapine	12/60/100mg	60s	200,000
Stavudine/Lamivudine/Nevirapine	30/150/200mg	60s	50,000
Zidovudine/Lamivudine	60/30mg	60s	138,000
Zidovudine/Lamivudine	300/150mg	60s	25,000
Zidovudine/Lamivudine (dispersible)	60/30mg	60s	30,000
Zidovudine/Lamivudine/Nevirapine	60/30/50mg	60s	556,500
Zidovudine/Lamivudine/Nevirapine	300/150/200mg	60s	46,400

Note: The figures above represent initial global forecasts only. Actual purchase volumes may vary. Please contact CHAI directly to discuss anticipated volumes.

† All liquid and syrup formulations must be supplied with a syringe or another measuring device. If appropriate, the price quoted for the formulation must be costed separate to that of the syringe or measuring device also.

\* Due to availability concerns and low volumes projected for 2011, CHAI will combine volumes for all of the didanosine (ddI) buffered formulations available under the Pediatric Project (i.e., 25mg and 50mg) for the purposes of manufacturer selection and will select up to two (2) manufacturers (a primary and a secondary) to supply these formulations to the Pediatrics Project. Manufacturers who only produce a subset of these formulations will be considered and are invited to respond to this letter.

\*\* Due to availability concerns and low volumes projected for 2011, CHAI will combine volumes for all of the didanosine (ddI) enteric coated formulations (i.e., 125mg, 200 mg, 250mg) together across both the UNTAID Pediatrics Project and Second-Line Project for the purposes of manufacturer selection. CHAI will choose up to two (2) manufacturers (a primary and a secondary) to supply all ddI enteric coated formulations. Manufacturers who only produce a subset of these formulations will be considered and are invited to respond to this letter.

Products marked “N/A” are expected to be procured in small volumes based on specific requests from beneficiaries. The volume for each product assumes packaging as indicated, but these assumptions are for illustrative purposes only.

## B. Low volume Pediatric ARVs which may be selected for supply by one supplier

<b>Formulations</b>	<b>Strength</b>	<b>Pack Size</b>
Abacavir (ABC)	60mg	60s
Efavirenz (EFV)	100mg	30s
Didanosine EC (DDI)	125mg	60s
Didanosine EC (DDI)	200mg	60s

## C. BENEFICIARY COUNTRIES

Angola  
Benin  
Botswana  
Burkina Faso  
Burundi  
Cambodia  
Cameroon  
China  
Cote d'Ivoire  
Dominican Republic  
Democratic Republic of the Congo  
Ethiopia  
Guyana  
Haiti  
India  
Jamaica  
Kenya  
Lesotho  
Liberia  
Malawi  
Mali  
Mozambique  
Namibia  
Nigeria  
Organization of Eastern Caribbean States (OECS)\*  
Papua New Guinea  
Rwanda  
Senegal  
Swaziland  
Tanzania  
Togo  
Uganda  
Vietnam  
Zambia  
Zimbabwe

\* Beneficiary countries of the Organization of Eastern Caribbean States includes six beneficiary countries (Antigua & Barbuda, Dominica, Grenada, St. Kitts & Nevis, St. Lucia and St. Vincent and the Grenadines).

## D. INSTRUCTIONS FOR TEMPLATE FOR COST-PLUS DISCLOSURE

**CHAI will only engage in cost-plus negotiations on a sub-set of formulations, those listed below;** for other formulations, manufacturers can only make a traditional price proposal.

**Please note that CHAI has reduced the cost-plus requirements since 2009, and that less data will be required than in years past.** Requirements are described in Schedule 9 and on the accompanying cost-plus template.

Manufacturers may elect to engage in cost-plus price negotiations for any or all of the four product categories listed below. Should a Manufacturer elect to engage in cost-plus price negotiations for a category, product cost information, as described in Schedule 9, must be provided for all products in that category. The category or categories selected for cost-plus negotiations should be clearly identified in the Manufacturers EOI letter.

The cost template for pediatric formulations has been provided in an excel file accompanying this letter.

With the advance agreement of CHAI, Manufacturers may make minor adjustments to the template as necessary to reflect internal cost accounting. Manufacturers should notify CHAI of any intention to modify the template at least one week before submission of an EOI.

### **Pediatric ARV Product Categories**

#### Category P1: Protease inhibitors

Lopinavir/Ritonavir (LPV/r)	80+20mg/ml	300ml
Lopinavir/Ritonavir (LPV/r)	200/50mg	120s
Lopinavir/Ritonavir (LPV/r)	100/25mg	120s

#### Category P2: Didanosine products

Didanosine (DDI)	25mg	60s
Didanosine (DDI)	50mg	60s
Didanosine (DDI)	100mg	60s
Didanosine (DDI)	2mg or 10mg/ml	200ml
Didanosine (DDI) EC	125mg	60s
Didanosine (DDI) EC	200mg	60s
Didanosine (DDI) EC	250mg	60s

#### Category P3: Efavirenz products

Efavirenz (EFV)	30mg/ml	180ml
Efavirenz (EFV)	50 mg	30s
Efavirenz (EFV)	100 mg	60s
Efavirenz (EFV)	200 mg	90s
Efavirenz (EFV) – scored tab	200 mg	90s

#### Category P4: Zidovudine products

Zidovudine (AZT)	50mg/5ml	240ml
Zidovudine (AZT)	100mg	100s
Zidovudine (AZT)	300mg	60s
Zidovudine-lamivudine-nevirapine (AZT/3TC/NVP)	300/150/200mg	60s
Zidovudine-lamivudine (AZT/3TC)	300/150mg	60s
Zidovudine-lamivudine-nevirapine (AZT/3TC/NVP)	60/30/50mg	60s
Zidovudine-lamivudine	60/30mg	60s

(AZT/3TC)		
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**Description of cost-plus data required for each formulation**

See Schedule 9.

## HISTORICAL VOLUMES FOR THE UNITAID PEDIATRIC PROJECT (in packs)

2007 order quantities:

Item	Cote Dominican																			
	Benin	Botswana	Burkina Faso	Burundi	Cambodia	Cameroon	China	d'Ivoire	D R Congo	Republic	Ethiopia	Guyana	India	Jamaica	Kenya	Lesotho	Liberia	Malawi	Mali	Mozambique
d4T (1mg/ml)				3	300		3,500		111	786	5,000					92		3,150		
d4T (15mg)			178	36	4,667	2,597			1,085						8,000	3,620		125	1,198	
d4T (20mg)			214	265	5,617	5,991			1,650	72					61,830	6,841		45	1,318	
d4T (30mg)									273		500				304			45		
d4T (40mg)																				
AZT (50mg/5ml)		1,200	300		4,460	12,649	31,100	13,208	12,518	9,432	35,000			11,875	3,000	39,692		5,520	5,396	
AZT (100mg)		5,000	1,230	192	2,600	4,205	3,743		13,846	955	27,895	1,782		850	49,638	12,939	689	1,625	509	
AZT (300mg)			33		300	926			2,022	576					2,896	2,325		470	472	
3TC (50mg/5ml)		2,700	1,444	149	8,000	15,008	40,315		23,698	8,004	9,970	1,197		9,200	88,099	25,583	850	4,985	2,283	
3TC (150mg)		2,500	1,582	449		7,225	9,802		13,175		17,000	39		200	9,953	18,783	366	2,085	2,904	1,134
NVP (50mg/5ml)		2,800	401	2,700		15,988	13,602		6,829	7,590	10,000				128,649	19,463	216	4,544	2,618	928
NVP (200mg)		14,600	625	242		2,839			18,162	72	11,900				26,316	6,738	233	520	1,279	
EFV (30mg/ml)																				
EFV (50mg)			1,396	453	8,972	9,476	5,040		2,449		13,000				77,756	9,890	1,683	1,400	888	3,840
EFV (200mg)			834		3,482	2,890	2,040		2,041	236	5,233	299	16,301		32,926	5,906	456	570	196	1,680
NFV (50mg/g)																				
NFV (250mg)																				103
3TC (20mg) + d4T (5mg) + NVP (35mg)														1,200						105,539
3TC (30mg) + d4T (6mg) + NVP (50mg)	187		3,683	18	5,335	10,913			3,089		5,400		130,214			3,387	655	22,135	4,087	
3TC (40mg) + d4T (10mg) + NVP (70mg)													268,864							
3TC (60mg) + d4T (12mg) + NVP (100mg)	212		3,203	33	16,335	14,114			7,010		22,000	616			2,500	5,713	1,840	32,824	2,316	
3TC (150mg) + d4T (30mg) + NVP (200mg)									123											78,060
3TC (150mg) + d4T (40mg) + NVP (200mg)																				
3TC (20mg) + d4T (5mg)																				
3TC (30mg) + d4T (6mg)						138			3,456		1,497		53,707			400	736	1,353		
3TC (40mg) + d4T (10mg)													39,291							
3TC (60mg) + d4T (12mg)						752			8,971		6,397					697	2,076	1,210		
3TC (150mg) + d4T (30mg)									93											13,710
3TC (150mg) + d4T (40mg)																				
3TC (150mg) + AZT (300mg) + NVP (200mg)																				435
3TC (150mg) + AZT (300mg)											72									795
3TC (150mg) + AZT (300mg) + ABC (300mg)							600													
ABC (20mg/ml)		84		8	444	265	1,550		23	575		89			9,206	228	703	565	175	1,540
ABC (300mg)		500		763	303	257	920		15		452			100		101		1,179		
DDI (2g or 10mg/ml)									2											48
DDI (25mg)		3,260	447	16	400	482			94		2,183	103			5,000	425	204	586	1,638	
DDI (50mg)		2,640	149	11	933	659			56	432							127	268	1,417	3,640
DDI (100mg)		5,000	60	4	1,050	393			11	30		53			1,600		95	388	377	
DDI (125mg)																				1,423
DDI (150mg)																				
DDI (200mg)			4																	364
DDI (200mg) EC																				853
DDI (250mg) EC																				
LPV/r (80 + 20 mg / ml)					340	690		1,000		154		150		80		44	30	120	340	490
LPV/r (100/25mg)																				
LPV/r (133/33mg)		40		20		1,140				180						22	40		60	
LPV/r (200/50mg)						640	1,141				410	20				200	120	1,200	240	

Item	Papua New Guinea												TOTAL
	Namibia	Nigeria	OECS	Guinea	Rwanda	Senegal	Swaziland	Tanzania	Uganda	Vietnam	Zambia	Zimbabwe	
d4T (1mg/ml)	10	10,919			1,836		42		10,750	24,921	10,000		<b>71,420</b>
d4T (15mg)	3,400	500				303	2,000	8,316	6,439	3,400	7,500		<b>53,364</b>
d4T (20mg)	4,000	2,473				633	1,923		6,706	2,500	13,796		<b>115,874</b>
d4T (30mg)		6,777							4,232				<b>12,131</b>
d4T (40mg)									250				<b>250</b>
AZT (50mg/5ml)	4,500	44,977	2,054		458	628	1,532		39,424	7,800	19,980	29,782	<b>336,485</b>
AZT (100mg)	17,350	205	224		1,014	719	2,124		10,353	1,800	9,000	2,971	<b>173,458</b>
AZT (300mg)	330	3,117			544	172	423		2,160		13,260		<b>30,026</b>
3TC (50mg/5ml)	2,350	10,000	1,354		13,945	203	2,000	140,227	32,270	19,200	38,000	12,947	<b>513,981</b>
3TC (150mg)	1,200	29,472	330		1,524	1,275	3,953		26,127		70,382		<b>221,460</b>
NVP (50mg/5ml)	2,800	8,850	141		24,901	396	7,541	99,333	36,515	24,000	30,000	10,136	<b>460,941</b>
NVP (200mg)	1,550	41,268	333		28,978	947	4,032		15,370			32	<b>176,036</b>
EFV (30mg/ml)		1,500							2,638				<b>4,138</b>
EFV (50mg)	750	19,703			30,150	515	355	2,221	10,667	7,200	14,324	13,593	<b>235,721</b>
EFV (200mg)		2,854			12,084	162	2,092	9,242	15,236	600	4,350	4,999	<b>126,709</b>
NFV (50mg/g)				20						53			<b>73</b>
NFV (250mg)				3		0				8			<b>114</b>
3TC (20mg) + d4T (5mg) + NVP (35mg)									1,171				<b>107,910</b>
3TC (30mg) + d4T (6mg) + NVP (50mg)	119	12,448		2,126		163	951	8,563	9,644	3,500	30,297	52,609	<b>309,523</b>
3TC (40mg) + d4T (10mg) + NVP (70mg)				1,688					1,244				<b>271,796</b>
3TC (60mg) + d4T (12mg) + NVP (100mg)	836	29,604				1,057	1,043	29,534	13,988	3,500	45,440	75,966	<b>309,684</b>
3TC (150mg) + d4T (30mg) + NVP (200mg)					14,732				1,901				<b>94,816</b>
3TC (150mg) + d4T (40mg) + NVP (200mg)					7,713				120				<b>7,833</b>
3TC (20mg) + d4T (5mg)													<b>0</b>
3TC (30mg) + d4T (6mg)	57	2,662		773			600		516			5,573	<b>71,468</b>
3TC (40mg) + d4T (10mg)													<b>39,291</b>
3TC (60mg) + d4T (12mg)	415	6,686					650		318			9,398	<b>37,570</b>
3TC (150mg) + d4T (30mg)					16,850				252				<b>30,905</b>
3TC (150mg) + d4T (40mg)					862								<b>862</b>
3TC (150mg) + AZT (300mg) + NVP (200mg)					7,292				3,712			654	<b>12,093</b>
3TC (150mg) + AZT (300mg)		23,965	31		17,861				14,904				<b>57,628</b>
3TC (150mg) + AZT (300mg) + ABC (300mg)													<b>600</b>
ABC (20mg/ml)		2,747		21	110		43		2,098	1,100	1,400	982	<b>23,956</b>
ABC (300mg)		18	16	7	357		19		1,335	400		1,022	<b>7,764</b>
DDI (2g or 10mg/ml)			120				250		26				<b>446</b>
DDI (25mg)	80	1,264				215	95	2,595	2,030			3,171	<b>24,288</b>
DDI (50mg)		1,038			210	207	25		854	500		2,599	<b>15,765</b>
DDI (100mg)		305			47	57			1,905				<b>11,375</b>
DDI (125mg)													<b>1,423</b>
DDI (150mg)		10											<b>10</b>
DDI (200mg)	198			21				573					<b>1,160</b>
DDI (200mg) EC													<b>853</b>
DDI (250mg) EC			16				400						<b>416</b>
LPV/r (80 + 20 mg / ml)		570		5		60	200		1,297	280	900	410	<b>7,160</b>
LPV/r (100/25mg)		200											<b>200</b>
LPV/r (133/33mg)			42		60	40			160	100			<b>1,904</b>
LPV/r (200/50mg)		800	31		120	80	500		2,334			680	<b>8,516</b>

2008 order quantities:

Item	Angola	Benin	Botswana	Burkina Faso	Burundi	Cambodia	Cameroon	China	Cote d'Ivoire	D R Congo	Dominican Republic	Ethiopia	Guyana	India	Jamaica	Kenya	Lesotho
d4T (1mg/ml)			4,729			250	6,150		10,250	294	300	18,349					50
d4T (15mg)			25,373	500		1,335				607	200	6,000	245			23,000	310
d4T (20mg)			9,111	1,200	510	7,807			2,680	884	200	11,000				15,000	
d4T (30mg)			5,346							329	24						
d4T (40mg)																	
AZT (50mg/5ml)	26,336	1,500	26,850		4,600	3,000	8,500	17,125	4,043	1,406	1,308	125,500				172,996	9,618
AZT (100mg)			15,413	200	1,700	1,549				1,231	1,868	13,000	1,041			98,798	3,000
AZT (300mg)							471					4,500					
3TC (50mg/5ml)	16,098		48,512		2,302	13,893	6,000	17,875	10,881	1,312		96,000	9,137			131,129	12,121
3TC (150mg)			39,274		1,068	5,168		15,750		1,369	981					20,000	2,500
NVP (50mg/5ml)	9,353		8,000		2,998	3,230	12,500	21,250	3,665	3,024		76,500	734			76,050	
NVP (200mg)			23,043		5,099		2,823			4,737	900					40,000	2,325
EFV (30mg/ml)							6,300		10,233			7,500					
EFV (50mg)	2,036	670		3,000	3,338	4,000		5,000		2,662	1,826	18,000	76	20,002		18,723	9,640
EFV (200mg)	1,231	690		800	1,500	665	3,000	1,500		1,091	1,033	10,900				4,880	2,786
3TC (30mg) + d4T (6mg) + NVP (50mg)		240		1,500	350	2,000				2,963	30	17,200				19,500	4,001
3TC (60mg) + d4T (12mg) + NVP (100mg)		335		2,500	980	5,321				8,326	185	33,500	136				5,664
3TC (150mg) + d4T (30mg) + NVP (200mg)										30							
3TC (150mg) + d4T (40mg) + NVP (200mg)																	
3TC (30mg) + d4T (6mg)		110					530			1,561	305	12,000					9,705
3TC (60mg) + d4T (12mg)		154					1,856			4,390	1,305	19,955	300				4,079
3TC (150mg) + d4T (30mg)																	
3TC (150mg) + d4T (40mg)																	
3TC (30mg) + AZT (60mg) + NVP (50mg)										15,601	3,682				525	10,000	3,800
3TC (150mg) + AZT (300mg) + NVP (200mg)										1,009	153						
3TC (30mg) + AZT (60mg)										7,275	3,808				40		14,617
3TC (150mg) + AZT (300mg)			10,509							748	568						
3TC (30mg) + ABC (60mg)																	
ABC (20mg/ml)	423	50	1,578				1,323			22	50	1,600	215			12,716	
ABC (60mg)																	349
ABC (300mg)			9,154			300	592			34	344						30
DDI (2g or 10mg/ml)										4	80	850					21
DDI (25mg)	364		5,460			543	826			118	832		96				75
DDI (50mg)		25	5,387			522	1,200		1,780	81	483	500					328
DDI (100mg)			5,142	250		167	880			33	354	1,250	97				
DDI (200mg)											170						
DDI (200mg) EC																	
LPV/r (80 + 20 mg / ml)	603		1,478	100		150	1,410		680	27	915	1,175				1,000	242
LPV/r (100/25mg)	995	220	4,000				900			55							494
LPV/r (133/33mg)							644			20			83				
LPV/r (200/50mg)			14,774				240			56	230						120

Item	Papua New															TOTAL	
	Liberia	Malawi	Mali	Mozambique	Namibia	Nigeria	OECS	Guinea	Rwanda	Senegal	Swaziland	Tanzania	Uganda	Vietnam	Zambia		Zimbabwe
d4T (1mg/ml)			1,260	300	1,220	15,570		486	10,600			1,478	11,053	3,000	63,589		<b>148,928</b>
d4T (15mg)			240			1,216		80	540	229	1,620		2,642		15,684		<b>79,821</b>
d4T (20mg)			300			23,581		126		515	3,585		8,558	1,000	21,384		<b>107,441</b>
d4T (30mg)			300			2,794		10		397	1,000		3,679	300			<b>14,179</b>
d4T (40mg)													60				<b>60</b>
AZT (50mg/5ml)	1,690	228	1,215	16,000	20,800	296,892	668	905	37,558	2,000	26,430	179,342	75,286	2,000	33,960		<b>1,097,756</b>
AZT (100mg)	525	268	6,515		4,550	22,674	389	445		2,835	17,050	41,764	36,569	1,500	20,216		<b>293,100</b>
AZT (300mg)		1,315	575			7,250	44						10,865		12,100		<b>37,120</b>
3TC (50mg/5ml)	1,024	160	2,000	3,660	16,808	259,812	450	744	14,105	1,812	42,417	40,506	46,156	2,150	37,673		<b>834,737</b>
3TC (150mg)	350	360	1,500	860	3,000	6,500	217	97	7,522	1,871	13,500		25,116	3,500	30,000		<b>180,503</b>
NVP (50mg/5ml)	1,498	34	2,500	10,016	15,200	211,823	480	1,765	11,520	1,400	12,100	70,180	37,012		80,784	2,052	<b>675,668</b>
NVP (200mg)	250	681	2,800	700		9,600	338	20		700	18,345		27,916	2,500			<b>142,777</b>
EFV (30mg/ml)			8,000		500	2,440			1,286				3,570				<b>39,829</b>
EFV (50mg)	1,350	576	1,000		4,800	55,858	6	47		981	2,696	33,685	24,826	5,500	17,090		<b>237,388</b>
EFV (200mg)	900	948	800	1,113	2,300	14,820	4	78		0	1,400		15,534	1,980	8,802		<b>78,755</b>
3TC (30mg) + d4T (6mg) + NVP (50mg)	712	82,247	249	52,665	2,150	33,551			16,421	75	4,600	78,564	39,248	2,600	7,000	70,353	<b>438,219</b>
3TC (60mg) + d4T (12mg) + NVP (100mg)	533	19,964	500		16,100	49,387		1,195	28,318	147	12,550	108,067	32,936	8,000	12,349	104,804	<b>451,797</b>
3TC (150mg) + d4T (30mg) + NVP (200mg)	500		170	43,827		1,675			21,978				9,644				<b>77,824</b>
3TC (150mg) + d4T (40mg) + NVP (200mg)													315				<b>315</b>
3TC (30mg) + d4T (6mg)	800	1,689		7,793	950	5,036			4,383		830	33,595	4,260			14,158	<b>97,705</b>
3TC (60mg) + d4T (12mg)	300	1,050			6,900	5,469		292	12,321		977		4,629			16,668	<b>80,645</b>
3TC (150mg) + d4T (30mg)				3,477		630		300	3,367				1,596				<b>9,370</b>
3TC (150mg) + d4T (40mg)									350								<b>350</b>
3TC (30mg) + AZT (60mg) + NVP (50mg)	738			9,103		97,764	180	580		1,875			20,410			116,027	<b>280,285</b>
3TC (150mg) + AZT (300mg) + NVP (200mg)				6,814			69		10,286				16,527				<b>34,858</b>
3TC (30mg) + AZT (60mg)	447			2,418		31,481		285					4,701			17,568	<b>82,640</b>
3TC (150mg) + AZT (300mg)	450		1,500	1,672	2,000	10,610	94		7,412				41,400				<b>76,963</b>
3TC (30mg) + ABC (60mg)													9				<b>9</b>
ABC (20mg/ml)	249	180	189		264	13,305	37	249		25	286	2,397	4,279	300	6,971		<b>46,708</b>
ABC (60mg)				4,622									27				<b>4,998</b>
ABC (300mg)		166	288	1,379		815	53				1,300		3,246		190		<b>17,891</b>
DDI (2g or 10mg/ml)		6			30	290		25			60		67				<b>1,433</b>
DDI (25mg)		564				2,957	64	51		167	300	1,980	3,376		2,686		<b>20,459</b>
DDI (50mg)		341	733		950	1,078	129	26	172	114	1,000		833				<b>15,682</b>
DDI (100mg)	178	138	355		280	358	23	13			618		2,592		3,008		<b>15,736</b>
DDI (200mg)						76	19		50				592				<b>907</b>
DDI (200mg) EC													150				<b>150</b>
LPV/r (80 + 20 mg / ml)	60	243	250		150	3,949		30			1,000	470	862	200		265	<b>15,259</b>
LPV/r (100/25mg)	73		675	4,213		1,722		93		150			2,717	1,100		3,200	<b>20,607</b>
LPV/r (133/33mg)	60						4				165						<b>976</b>
LPV/r (200/50mg)	60	1,282		1,645	525	5,755	44				680		1,290			302	<b>27,003</b>

## 2009 order quantities:

Item	Cote D R Dominican																
	Angola	Benin	Botswana	Burkina Faso	Burundi	Cambodia	Cameroon	China	d'Ivoire	Congo	Republic	Ethiopia	Guyana	India	Jamaica	Kenya	Lesotho
d4T (1mg/ml)			6,750	641	3,854		7,638		6,650	262	1,000	8,000					
d4T (15mg)			8,000	20	606	1,516	800		1,728	544	10		1,645			10,000	
d4T (20mg)	150	11,461	1,200	1,886	2,627	1,100	600	2,376	1,222	114						15,000	
d4T (30mg)			6,873	851						295	60						
AZT (50mg/5ml)		1,900	21,000	1,960	4,962	173	28,588	7,800	5,356	1,416	4,330		2,269			101,982	
AZT (100mg)				900	65	3,882	3,300			2,407	900		335			88,056	
AZT (300mg)		600		255			1,768					5,000					
3TC (50mg/5ml)	2,030	52,536	2,750	3,860	733	14,921	11,700		2,671	3,750	10,000					207,983	
3TC (150mg)	2,560	20,548	4,255	509	22,769	4,946	24,240		2,271	942							
NVP (200mg)		1,100	28,424	1,710		14,819	2,633		3,964	800							
NVP (50mg/5ml)	2,200	5,695	1,300	7,293	871	16,000	9,000	1,208	3,030	1,615		3,156				144,998	
EFV (30mg/ml)							5,563					10,000					
EFV (50mg)		1,600		6,800	4,690	19,470	1,200	13,940	5,984	2,217	13,000	251	19,384			100,000	17,285
EFV (200mg)	207	910		1,200	2,539	4,604		6,050	1,785	1,622	1,242	6,000	519			40,500	6,758
EFV (200mg) - Scored Tab			900											10,756			2,057
3TC (30mg) + d4T (6mg) + NVP (50mg)		100		870		7,710	6,000		3,478	276	19,994		493,537				21,269
3TC (60mg) + d4T (12mg) + NVP (100mg)		400		5,100		82,727	9,604		9,772	171	48,000					109,994	
3TC (150mg) + d4T (30mg) + NVP (200mg)				425							50						
3TC (30mg) + d4T (6mg)		350				465	850		1,252	463			83,393				9,853
3TC (60mg) + d4T (12mg)		680				3,103	1,000		3,520	222	4,500						
3TC (150mg) + d4T (30mg)				85						250							
3TC (30mg) + AZT (60mg) + NVP (50mg)		800				388	2,000		44,014	1,015	55,000		80,012			157,004	34,697
3TC (150mg) + AZT (300mg) + NVP (200mg)									2,269	1,003							
3TC (30mg) + AZT (60mg)		3,100	4,400			1,277	2,000		8,725	3,125	50,000		12,521	230			33,681
3TC (150mg) + AZT (300mg)			17,100	1,701					521	1,250							
3TC (30mg) + ABC (60mg)													9,398			42,000	
ABC (20mg/ml)	168	250	2,310	120	43	149	3,900	930	672	253	500	800	208			105,013	
ABC (60mg)										1,602	500						1,329
ABC (300mg)			6,366	510				3,600		170	496						
DDI (2g or 10mg/ml)	2,245									5	100	1,000					
DDI (25mg)			4,646			1,700	400		886	1,364	285	1,000	115			12,600	1,247
DDI (50mg)		50	1,212	110		1,097	500		4,918	867	250					5,000	
DDI (100mg)		200			101	1,476	1,273			356			162				
DDI (200mg)				400	227				2,144								42
DDI (125mg) EC														2,376			
DDI (200mg) EC					70						287			1,032			61
DDI (250mg) EC						3,450					374						
LPV/r (80 + 20 mg / ml)		200		570	40	80	240	1,800	1,300	270	1,050	500	40			2,800	190
LPV/r (100/25mg)		1,200	4,575		60	709	2,520	720		2,389	4,120		3,793			11,800	1,786
LPV/r (200/50mg)			13,802	425						20	1,050						

Item	Papua New																	TOTAL
	Liberia	Malawi	Mali	Mozambique	Namibia	Nigeria	OECS	Guinea	Rwanda	Senegal	Swaziland	Tanzania	Togo	Uganda	Vietnam	Zambia	Zimbabwe	
d4T (1mg/ml)			1,000		1,400	6,073		800	2,900					914	2,300	4,051		54,233
d4T (15mg)			522			610		100		200	100			265	1,400			28,066
d4T (20mg)			600			7,457				400	350			2,083	2,800			51,426
d4T (30mg)			275			320				400	200			868				10,142
AZT (50mg/5ml)		32,413	7,000		3,072	50,055	669	486	4,705	1,400					5,400	17,389		304,325
AZT (100mg)		816	2,000			18,730		351		800		123,934	276	2,000	2,000	7,625		258,377
AZT (300mg)			533			4,000	15							8,804				20,975
3TC (50mg/5ml)	341	1,745	5,800	3,000		21,800	494	1,129	9,949	1,200		91,091		1,020	6,500	18,447		475,450
3TC (150mg)		2,817	1,600				494		1,029	700	988			3,293				93,961
NVP (200mg)		4,377	1,800			1,497	227	122	361	500	3,102		200	14,123				79,759
NVP (50mg/5ml)	544	982	4,700		3,072	20,780	190	926	28,053	700				4,980	4,500	17,721	1,810	285,324
EFV (30mg/ml)			1,400		150													17,113
EFV (50mg)		612	1,650	3,948		25,202		680		100	8,300		2,300	11,618	5,500	18,845	8,770	293,346
EFV (200mg)		2,331	415	480	1,800	4,600			2,963	600	2,150	9,982		2,000	2,100	17,724	1,361	122,442
EFV (200mg) - Scored Tab		338			1,800	3,927								17,833				37,611
3TC (30mg) + d4T (6mg) + NVP (50mg)	445	78,073	2,260	68,965	2,170	14,329		3,484		100	650	34,639	3,624	11,355	3,500	4,758	33,146	814,732
3TC (60mg) + d4T (12mg) + NVP (100mg)	165	64,536	5,240		4,424	22,937		5,793		200	23,000	10,467	18,487	21,500	91,956	114,265		648,738
3TC (150mg) + d4T (30mg) + NVP (200mg)			496	64,895										5,468				71,334
3TC (30mg) + d4T (6mg)	44	13,652		2,000	1,610	3,934		320			1,214		300	8,290			4,101	132,091
3TC (60mg) + d4T (12mg)	80	2,364			3,080	5,012					8,354		750	6,482		7,000	5,465	51,612
3TC (150mg) + d4T (30mg)				14,496									250	2,354				17,435
3TC (30mg) + AZT (60mg) + NVP (50mg)	1,317		3,025			149,423		3,211	9,570		30,370		1,000	73,640	4,000			657,956
3TC (150mg) + AZT (300mg) + NVP (200mg)				18,152										67,272				88,696
3TC (30mg) + AZT (60mg)	124		400	4,770		34,292		100	2,530		10,950		600	38,044			3,655	214,524
3TC (150mg) + AZT (300mg)		334	270	4,645			29			300				35,075				61,225
3TC (30mg) + ABC (60mg)						5,948			690					4,690				62,726
ABC (20mg/ml)	435	370	1,050			4,509			1,976	8		2,685		858	1,150	4,577	1,414	134,348
ABC (60mg)	74			2,152		515			100				400	75				6,747
ABC (300mg)		2,294		1,828			29				489			500				16,282
DDI (2g or 10mg/ml)		14				125		50				2,000						5,539
DDI (25mg)		3,121	100	2,077		1,045				200	160		610	949	1,300	2,002	434	36,241
DDI (50mg)		648	1,700			205				100	5		650	491	500		1,519	19,822
DDI (100mg)	74		550			1,060					256		100			5,774		11,382
DDI (200mg)						555								52				3,420
DDI (125mg) EC																		2,376
DDI (200mg) EC		1,780				520			50		140			2,123				6,063
DDI (250mg) EC							15				375		150					4,364
LPV/r (80 + 20 mg / ml)		759	630	770	340	2,590		70	1,040	350		550	380	1,060	700	2,760		21,079
LPV/r (100/25mg)	37	1,440	600	1,200		6,800		60	1,080	320	4,740		520	9,931	1,480	320	12,000	74,200
LPV/r (200/50mg)		2,205			4,000		43				1,131			960				23,636

2010 YTD order quantities (through October 6, 2010):

Item	Angola	Benin	Botswana	Burkina Faso	Burundi	Cambodia	Cameroon	China	Cote d'Ivoire	Congo	D R Republic	Dominican Republic	Ethiopia	Guyana	Haiti	India	Jamaica	Kenya	Lesotho
d4T (1mg/ml)				2,000	2,754		1,500		22,040			800							
d4T (15mg)			3,300	500	203				864			15							
d4T (20mg)			8,384	500	739	504	500	2,430	5,724			60							
d4T (30mg)												200							
AZT (50mg/5ml)	9,600	3,200	10,632		1,077			11,960	8,034	2,500	2,000							65,000	
AZT (100mg)				200	1,450					1,800									
AZT (300mg)		3,500					600												
3TC (50mg/5ml)	8,229	1,500	10,994	4,500	3,022	1,499		8,505	10,395	500	2,878			65				79,000	
3TC (150mg)		1,200	3,245	3,000		1,985	5,000	11,846		1,500									
NVP (50mg/5ml)	14,909	3,900	5,273		1,653	36		9,720	6,912	1,000	660	16,800						102,000	
NVP (200mg)		2,500	8,248			2,513	600												
EFV (50mg)		1,300			2,795			7,290	4,200	5,000			26,856					10,000	
EFV (200mg)	531			560	7,714		300	2,916					11,070					22,000	
EFV (200mg) - Scored Tab				240			500		3,480	1,500							18,267		19,214
3TC (30mg) + d4T (6mg) + NVP (50mg)		100		1,900		767	2,000						14,800				94,620		28,519
3TC (60mg) + d4T (12mg) + NVP (100mg)		300		3,700	929		3,500				40	60,888		500					
3TC (150mg) + d4T (30mg) + NVP (200mg)										150									
3TC (30mg) + d4T (6mg)		150											9,194						13,266
3TC (60mg) + d4T (12mg)		200			929	13	1,500						17,886		650				
3TC (150mg) + d4T (30mg)																			
3TC (30mg) + AZT (60mg) + NVP (50mg)	467	500		1,500	4,056	1,459	1,500	7,293		90,000			33,734		7,100	93,394			34,467
3TC (150mg) + AZT (300mg) + NVP (200mg)							500			4,000									
3TC (30mg) + AZT (60mg)		800		500	1,933	1,009	500			20,500			8,000		11,200	20,353		4,998	
3TC (150mg) + AZT (300mg)			26,400				400			900									
3TC (30mg) + ABC (60mg)										500						11,020		71,243	
ABC (20mg/ml)	611	100			130	115		780	704	500	100	2,196						39,500	
ABC (60mg)					60														
ABC (300mg)		300	7,348					1,823			300	750							
DDI (25mg)							500												
DDI (50mg)				300			200											2,000	
DDI (100mg)			776																
DDI (125mg) EC		300		300		210	250			500						5,334		5,000	99
DDI (200mg) EC		200		200	361	466	450			500						1,896			68
DDI (250mg) EC		100											1,000						
LPV/r (80 + 20 mg / ml)	154	200	500		30		1,000	1,370	980	1,000	80	2,300				1,200		2,500	690
LPV/r (100/25mg)			9,920		160	6,576	3,000	960		1,000						10,169			
LPV/r (200/50mg)		200	7,502																

Item	Papua New														TOTAL			
	Liberia	Malawi	Mali	Mozambique	Namibia	Nigeria	OECS	Guinea	Rwanda	Senegal	Swaziland	Tanzania	Togo	Uganda		Vietnam	Zambia	Zimbabwe
d4T (1mg/ml)			700					300						3,270	500			<b>33,864</b>
d4T (15mg)			1,000						300	100					200			<b>6,482</b>
d4T (20mg)			500						200	500	46,448				1,600			<b>68,089</b>
d4T (30mg)			400															<b>600</b>
AZT (50mg/5ml)			7,000			9,600		500	2,582	1,900			250	7,484	3,500	10,000		<b>156,819</b>
AZT (100mg)		2,038	600							2,100					5,000	5,194		<b>18,382</b>
AZT (300mg)			950				28			500				2,146				<b>7,724</b>
3TC (50mg/5ml)		459	3,500					500	8,703	2,798		54,543	250	4,775	5,500	19,778		<b>231,893</b>
3TC (150mg)		10,988	3,000				19			800	250			30				<b>42,863</b>
NVP (50mg/5ml)		869	4,000				233	328		5,700		84,014	250	7,202	4,500	4,000		<b>273,959</b>
NVP (200mg)		7,039	2,000				144			3,000	400			27,743				<b>54,187</b>
EFV (50mg)	102	1,768	1,100	4,080	1,200	14,410		500	3,780	1,000	6,000	4,805		17,165	11,600	16,993	3,116	<b>145,060</b>
EFV (200mg)			400	3,380					5,460	300			600		2,200	7,788	3,102	<b>68,321</b>
EFV (200mg) - Scored Tab		3,361	500			13,450				500				21,507				<b>82,519</b>
3TC (30mg) + d4T (6mg) + NVP (50mg)	237	38,602	2,100	78,426	3,200	5,540				600				28,404	1,300			<b>301,115</b>
3TC (60mg) + d4T (12mg) + NVP (100mg)	916	53,785	5,500		7,500	5,060				700	10,000	30,000	4,500	34,864	7,500	89,042	85,268	<b>404,492</b>
3TC (150mg) + d4T (30mg) + NVP (200mg)				81,307										219				<b>81,676</b>
3TC (30mg) + d4T (6mg)	90	1,216	300	5,666		3,805		500		200				7,932			15,620	<b>57,939</b>
3TC (60mg) + d4T (12mg)	355	2,939	600		1,000	4,160		400		200	2,500			7,068		2,800	3,186	<b>46,386</b>
3TC (150mg) + d4T (30mg)				15,666							780			303				<b>16,749</b>
3TC (30mg) + AZT (60mg) + NVP (50mg)	3,504	4,813	15,600	17,897		52,900		800	9,570	6,000	16,500	104,505	5,000	19,947	24,000			<b>556,506</b>
3TC (150mg) + AZT (300mg) + NVP (200mg)				20,498			80			300			800	20,239				<b>46,417</b>
3TC (30mg) + AZT (60mg)	451	1,155	1,000	5,850		30,186		1,300	2,530	5,900	6,900		1,500	11,468				<b>138,033</b>
3TC (150mg) + AZT (300mg)		47		4,444			40			1,500			200	24,735				<b>58,666</b>
3TC (30mg) + ABC (60mg)		876				5,300				500	175			20				<b>89,634</b>
ABC (20mg/ml)		344	1,500		1,020	1,300	23		3,296	450	980		500	1,748	1,900	10,905	382	<b>69,084</b>
ABC (60mg)				10,020					100					100				<b>10,280</b>
ABC (300mg)		4,049	600		400		22				255							<b>15,847</b>
DDI (25mg)		187		240						450		600	200	600				<b>2,777</b>
DDI (50mg)																		<b>2,500</b>
DDI (100mg)																		<b>776</b>
DDI (125mg) EC	77	3,842	300		6,000	260				400	325			1,852	900		1,181	<b>27,130</b>
DDI (200mg) EC		1,233	300			150				400	325			982	1,700		727	<b>9,958</b>
DDI (250mg) EC							48				240							<b>1,388</b>
LPV/r (80 + 20 mg / ml)		193	1,200		400	700	45			600	290		900	380	1,000		4,870	<b>22,582</b>
LPV/r (100/25mg)	40	917	3,100	6,604		1,600				1,600				1,290	1,960		9,169	<b>58,065</b>
LPV/r (200/50mg)		3,074	1,000		5,200		48				300							<b>17,324</b>

# SCHEDULE 2

## SECOND-LINE PROJECT

### Table of Contents

- A. List of UNITAID-financed second-line ARVs and indicative order volumes for March 1, 2011 through February 28, 2012
- B. List of second-line ARVs likely to be sourced from two secondary Manufacturers
- C. List of Beneficiary Countries
- D. Instructions for template for cost-plus negotiation disclosure
- E. Historical volumes for the UNITAID Second-Line Project.

### A. LIST OF UNITAID-FINANCED SECOND-LINE ARVS AND INDICATIVE ORDER VOLUMES FOR MARCH 1, 2011 THROUGH FEBRUARY 28, 2012

Formulation	Strength	Indicative Order Volumes (March 1, 2011 - Feb 28, 2012)
Abacavir	300mg	110,000
Atazanavir	300mg	60,000
Didanosine Enteric Coated	250mg	75,000
Didanosine Enteric Coated	400mg	
Lopinavir + Ritonavir	200mg + 50mg	475,000
Ritonavir tab (heat stable)	100mg	60,000
Tenofovir + Emtricitabine	300mg + 200mg	675,000
Tenofovir + Lamivudine	300mg + 300mg	
Tenofovir	300mg	25,000

\*Due to availability concerns and low volumes projected for 2011, CHAI will combine volumes for all of the didanosine (ddI) enteric coated formulations (i.e., 125mg, 200 mg, 250 mg and 400 mg) together across both the UNITAID Pediatrics Project and Second-Line Project for the purposes of manufacturer selection. CHAI will choose up to two (2) manufacturers (a primary and a secondary) to supply all ddI enteric coated formulations. Manufacturers who only produce a subset of these formulations will be considered and are invited to respond to this letter.

\*\* The division of volumes between the TDF + 3TC and TDF + FTC formulation is not yet quantifiable due to remaining uncertainty about the split between the two products in national regimens. Thus, only the projected combined volume for the two products are indicated above. Ongoing country forecasts will produce a final quantification of volumes for each formulation before orders are submitted.

### B. List of Products that may be sourced from a primary and two secondary Manufacturers

<u>Formulations</u>	<u>Strength</u>	<u>Pack Size</u>
Abacavir (ABC)	300mg	60s
Tenofovir (TDF)	300mg	30s
Tenofovir+Emtricitabine	300+200mg	30s
Tenofovir+Lamivudine	300+300mg	30s
Lopinavir/Ritonavir (LPV/r)	200/50mg	120s

**C. BENEFICIARY COUNTRIES OF SECOND LINE PROJECT**

Benin  
Botswana  
Burundi  
Cambodia  
Cameroon  
Chad  
Cote d'Ivoire  
Democratic Republic of Congo  
Ethiopia  
Ghana  
Haiti  
India  
Kenya  
Malawi  
Mali  
Mozambique  
Namibia  
Nigeria  
Rwanda  
Senegal  
Tanzania  
Togo  
Uganda  
Zambia  
Zimbabwe

**D. INSTRUCTIONS FOR TEMPLATE FOR COST-PLUS NEGOTIATION DISCLOSURE**

**CHAI will only engage in cost-plus negotiations on a sub-set of formulations, those listed below;** for other formulations, manufacturers can only make a traditional price proposal.

**Please note that CHAI has reduced the cost-plus requirements since 2009, and that less data will be required than in years past.** Requirements are described in Schedule 9 and on the accompanying cost-plus template.

Manufacturers may elect to engage in cost-plus price negotiations for any or all of the three product categories listed below. Should a Manufacturer elect to engage in cost-plus price negotiations for a category, product cost information, as described in Schedule 9, must be provided for all products in that category. The category or categories selected for cost-plus negotiations should be clearly identified in the Manufacturers EOI letter.

The cost template for second-line formulations has been provided in an excel file accompanying this letter.

With the advance agreement of CHAI, Manufacturers may make minor adjustments to the template as necessary to reflect internal cost accounting. Manufacturers should notify CHAI of any intention to modify the template at least one week before submission of an EOI.

## Second-Line ARV Product Categories

Category S1: Tenofovir products

TDF	300mg
TDF+FTC	300+200mg
TDF+3TC	300+300mg

Category S2: Protease inhibitors

LPV/r	200+50mg
ATV	300mg
RTV	100mg
ATV+RTV+(TDF+3TC)	300+100+(300+300)mg

## Description of cost-plus data required for each formulation

See Schedule 9

**E. HISTORICAL VOLUMES FOR THE UNITAID SECOND-LINE PROJECT (in packs)**

Item	Benin	Botswana	Burundi	Cambodia	Cameroon	Chad	Cote d'Ivoire	D R Congo	Ethiopia	Ghana	Haiti	India	Kenya	Malawi
<b>2007 (Mar 2007 to Feb 2008)</b>														
ABC 300mg	510	2,250	2,969	1,002	5,106	1,599	6,310	1,185	6,490	1,382	1,000			
ddI 250mg		3,170	1,277	1,504	10,213	3,198		593		800				
ddI 400mg		3,799	1,693	400		2,133		593		509	2,000		6,000	
LPV/r 200/50mg	126	37,861	3,832	5,200	10,290	4,808	4,800	1,185	18,220	971		2,160	13,000	8,830
TDF + FTC 300/200mg			742		3,000	295								
TDF + FTC 300/300mg					1,200	295						1,440		
TDF 300mg	126	32,787	318	6,910	3,032	3,143	718		21,550	145		720	15,300	8,820
<b>2008 (Mar 2008 to Feb 2009)</b>														
ABC 300mg	1,590	1,800	3,810	165	4,725	514		5,138					40,177	
ddI 250mg	2,575			2,200		1,028		2,569	3,000				6,000	
ddI 400mg	550		3,195	1,399	8,000	685		2,569	1,700		2,000		2,000	
LPV/r 200/50mg	110	35,266	4,288	9,550	14,750	1,541	8,000	5,138	10,005		2,000	12,150	98,004	10,870
TDF + FTC 300/200mg		50,512			1,280	300								
TDF + FTC 300/300mg	10				2,040	300						12,844	32,000	
TDF 300mg		12,628		15,000	2,664	600	2,200		12,000				150,764	10,028
Zidovudine 300mg												9,700		
<b>2009 (Mar 2009 to Feb 2010)</b>														
ABC 300mg		6,180	27,757		9,500	1,354	3,660	7,388	11,000		4,000		119,940	
ddI 250mg	1,170		2,763		5,300	200		3,694	9,500				23,000	
ddI 400mg	100		6,951	100	500	400		3,694	2,000		2,000		25,019	
LPV/r 200/50mg	1,760	68,349	5,810	30,364	10,000	1,900	16,140	7,388	35,015		6,995		154,997	
TDF + FTC 300/200mg		46,604			9,010	4,217					2,700			
TDF + FTC 300/300mg	800				10,998	250			6,000				279,384	
TDF 300mg			262	38,325	10,800	200					6,750		165,000	
Zidovudine 300mg												7,200		
<b>2010 YTD through Oct 1,</b>														
ABC 300mg		12,081	10,082		11,000	8,000		19,000			2,000		69,999	
ATV 300mg	300											6,000		
ddI 250mg			2,990	2,391	6,000	2,250		4,219			300			
ddI 400mg			5,464	333	5,500	2,500		16,000						
LPV/r 200/50mg		90,024	7,160	692	41,020	10,000		12,100			9,985	8,532	69,958	
RTV 100mg (heat stable)	300													
TDF + FTC 300/200mg		35,000			11,500	6,000								
TDF + FTC 300/300mg					8,500			1,500			5,500	16,100		
TDF 300mg			262	14,311	1,000	2,500					1,000			

Item	Mali	Mozambique	Namibia	Nigeria	Rwanda	Senegal	South					Zimbabwe	Grand Total
							Africa	Tanzania	Togo	Uganda	Zambia		
<b>2007 (Mar 2007 to Feb 2008)</b>													
ABC 300mg	2,600	13,800	146	2,639	8,932	695			4,584	2,141	6,575	1,115	73,030
ddI 250mg	1,500	3,200	434		2,057	4,620		7,639		1,286		4,553	46,044
ddI 400mg	300	3,050	179	2,046	1,674	4,620		6,373	4,584	2,143		2,684	44,780
LPV/r 200/50mg	11,077	13,560	3,560	9,894	9,280	12,603			8,890	25,760	28,840	11,560	246,307
TDF + FTC 300/200mg				11,799		632				185,040	161,550		363,058
TDF + FTC 300/300mg	1,570		20,529	14,925		347			7,641	4,424	5,100	4,990	62,461
TDF 300mg	1,300	3,120	236	8,996	3,643	6,317		240		1,721	5,000		124,142
<b>2008 (Mar 2008 to Feb 2009)</b>													
ABC 300mg	3,340	1,170	390	7,241	9,450					3,792	14,500	781	98,583
ddI 250mg	3,600	3,950	650		1,122			6,489		6,480		2,690	42,353
ddI 400mg		2,700	300	7,602	1,629			11,570		5,157		3,991	55,047
LPV/r 200/50mg	9,220	12,960		67,822	11,935			16,920		63,904	41,360	10,953	446,746
TDF + FTC 300/200mg				21,614						214,638	809,649		1,097,993
TDF + FTC 300/300mg	2,050		39,140	47,360						222,610		2,566	360,920
TDF 300mg	1,750	6,730	300	12,495	13,078	2,000				11,845		72	254,154
Zidovudine 300mg													9,700
<b>2009 (Mar 2009 to Feb 2010)</b>													
ABC 300mg	6,500	23,190	240	11,884	6,885	500	12,055	38,020	2,850	11,091	38,768	4,185	346,947
ddI 250mg	7,500	2,000		2,150	562	800		20,000	700	12,637		3,686	95,662
ddI 400mg		700		6,151	564	250		11,234	2,600	10,218		2,001	74,482
LPV/r 200/50mg	14,000	13,165	7,125	145,160	4,375	2,815		18,120	18,557	93,250	65,520	26,232	747,037
TDF + FTC 300/200mg				2,796		500				17,528	424,048		507,403
TDF + FTC 300/300mg	1,300		3,150	82,618		1,300			6,600	359,139	28,814	17,045	797,398
TDF 300mg	700	3,210		8,548	5,714					20,710			260,219
Zidovudine 300mg													7,200
<b>2010 YTD through Oct 1, 2010</b>													
ABC 300mg	3,000	19,131		8,050		1,750			4,400	16,478	27,232	4,508	216,711
ATV 300mg	3,010								7,500	6,449			23,259
ddI 250mg		2,200		1,450		4,500			400	6,255		2,282	35,237
ddI 400mg		3,140		150		2,000			4,700	8,348			48,135
LPV/r 200/50mg	7,000	21,574		147,000		8,000			20,510	84,047	113,344	22,062	673,008
RTV 100mg (heat stable)	3,010								7,500	6,919			17,729
TDF + FTC 300/200mg						1,200				10,288	284,500		348,488
TDF + FTC 300/300mg	4,200			20,000		7,800			15,500	311,275		16,438	406,813
TDF 300mg	1,300	8,320		1,000		2,000				573			32,266

## SCHEDULE 3

### Members of the CHAI Procurement Consortium (as of April 2010)

Note: The CHAI Procurement Consortium includes those countries that have signed an agreement with CHAI committing to follow standard procurement practices and to access negotiated prices consistent with applicable terms and conditions. Additional low or middle income countries interested in joining the Consortium can contact CHAI in writing.

Region	Country (71*)
<b>Africa</b>	Angola
	Benin
	Botswana
	Burkina Faso
	Burundi
	Cameroon
	Cape Verde
	Central African Republic
	Chad
	Cote d'Ivoire
	Democratic Republic of Congo
	Ethiopia
	Gambia
	Ghana
	Guinea Bissau
	Kenya
	Lesotho
	Liberia
	Mali
	Malawi
	Mauritius
	Morocco
	Mozambique
	Namibia
	Nigeria
	Rwanda
	São Tomé and Príncipe
	Senegal
	Seychelles
	South Africa
	Swaziland
	Tanzania
Togo	
Uganda	
Zambia	
Zimbabwe	
<b>Asia</b>	Bhutan
	Cambodia
	China
	India
	Indonesia
	Lao People's Democratic Republic
	Pakistan
	Papua New Guinea
	Sri Lanka
	Thailand
Vietnam	
<b>Eastern Europe</b>	Kazakhstan
	Kyrgyzstan
	Ukraine
<b>Latin America and the Caribbean</b>	Argentina
	Bahamas
	Barbados
	Belize
	Bolivia
	Brazil
Chile	

	Colombia
	Dominican Republic
	Ecuador
	El Salvador
	Guatemala
	Guyana
	Haiti
	Honduras
	Jamaica
	OECS*
	Panama
	Peru
	Suriname
	Trinidad & Tobago
	Turks & Caicos

\*The Organization of Eastern Caribbean States which is made up of six countries (Antigua & Barbuda, Dominica, Grenada, St. Kitts & Nevis, St. Lucia and St. Vincent and the Grenadines) and three territories (Anguilla, British Virgin Islands and Montserrat) is counted as one in this list.

## SCHEDULE 4

### **Mandatory Conditions of participation of Manufacturers**

Each Manufacturer must meet the following conditions, with respect to each product it proposes to supply, in order to participate in the project. **Manufacturers are required to sign and return a copy of this schedule with their EOI** as confirmation of their commitment to supply in accordance with the terms and conditions set out herein. This is not a substitute for the mandatory Master Supply Agreement (MSA) mentioned in Schedule 5 below.

1. Manufacturers must supply products that conform to the quality assurance standard set forth in Schedule 6 of the Manufacturer Letter. For the purpose of this Manufacturer selection process, Manufacturers of products that are not prequalified by WHO or other stringent regulatory authority must have submitted an application for approval together with a complete dossier for the product to the WHO or other stringent regulatory authority **by November 12, 2010**.

The relevant documents that are required to be submitted with the Manufacturer's EOI are set forth in Section 5 of the Manufacturer Letter.

2. Manufacturer agrees to comply with the obligations set out in Schedule 7 relating to quality control requirements for all products delivered under the Projects.
3. Manufacturers will provide to CHAI the registration status of the product (or application for waiver thereof), including the date of submission to or approval by each of these authorities, at the time of proposal and on an ongoing basis.
4. Manufacturer agrees to extend prices to additional countries that are not UNITAID beneficiaries for the second-line and pediatric projects, including, at a minimum, members of the CHAI Consortium (listed in Schedule 3).
5. The shelf life for the product should be provided to CHAI at the time of proposal, and the dispatch of the product must be conditioned on a minimum of 18 months or 75% of the total product shelf life remaining, whichever is greater, at the time of delivery
6. For facilities in which the product is manufactured and records associated with its manufacture for UNITAID-financed volumes, the Manufacturer must be willing to submit to a quality assurance audit by CHAI or its authorized representative or agent, which may include the Procurement Agent, prior to the first shipment of product and once per year thereafter.
7. Each Manufacturer must warrant to CHAI and UNITAID that the prices at which it proposes to sell product are not intended to be "predatory prices" or otherwise anti-competitive, and, in the event that CHAI or UNITAID has reasonable grounds to question this statement, the Manufacturer will grant CHAI or its representative access to records sufficient for CHAI and UNITAID to resolve their concerns.
8. Product(s) affected by an outstanding notice of concern, warning letter, import alert or other precautionary action by the WHO, U.S. FDA or other stringent regulatory authority, as designated by the International Conference on Harmonization (ICH), are ineligible for supply to the project. Manufacturers are required to inform CHAI and UNITAID in the EOI of any and all such actions against them by a stringent regulator,

even if the action in question does not directly affect products covered in this Manufacturer letter. CHAI and UNITAID reserve the right to revoke a Manufacturer's eligibility and suspend procurement at any time during the tender period if precautionary action affecting product(s) supplied to the project is taken by a stringent regulatory authority subsequent to Manufacturer selection.

9. If a Manufacturer is selected for a product (i.e., is either the primary or secondary Manufacturer or a member of the Manufacturer pool), in case of failure by the Manufacturer to perform under the terms and conditions of the purchase order, including but not limited to failure to make delivery of all or part of the goods by the agreed delivery date(s), the procurement agent may, after giving the Manufacturer reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights:
  - Procure all or part of the goods from another source(s), in which event the agent may hold the Manufacturer responsible for any excess cost occasioned thereby;
  - Refuse to accept delivery of all or part of the goods; and/or
  - Terminate the purchase order.
  
10. Each selected Manufacturer will be required to enter into a Master Supply Agreement with CHAI on behalf of UNITAID to commit to the agreed prices and terms on standard conditions consistent with applicable UNITAID requirements. In addition, each selected Manufacturer will be required to honor orders placed by the Procurement Agent on standard conditions that are substantially the same as those set forth in Schedule 5.

These and other conditions associated with the supply of a product will also be included in the agreement(s) between the procurement agents and the Manufacturer.

The terms and conditions described above are agreed and accepted.

Company Name: \_\_\_\_\_

Signed: \_\_\_\_\_

Typed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

## **SCHEDULE 5**

### **Standard Terms and Conditions of Product Procurement Under the UNITAID Second-Line Treatment Project and the UNITAID Pediatric Treatment Project**

Manufacturers will sign Master Supply Agreements (MSAs) with CHAI for products to be supplied as an outcome of this Tendering exercise. MSAs will establish a ceiling price for each product, and CHAI will use this price as a baseline when negotiating prices prior to instructing the Procurement Agent to issue Purchase Orders to Manufacturers.

Manufacturers will enter into an agreement with Procurement Agent at or below the ceiling prices set forth in the Master Supply Agreement and on terms and conditions set forth below.

#### **1. Acknowledgement Copy**

Acceptance of a purchase order (the "Purchase Order") shall constitute a binding contract with the Manufacturer, acknowledging (in writing or by email) receipt of the Purchase Order and its agreement to deliver the products by the date therein specified (the "Products"). The contract between the parties is subject only to the Master Supply Agreement and the terms and conditions detailed here below. In the event that any terms or conditions of Schedule 5 conflict with any terms or conditions of the Master Supply Agreement, the terms and conditions of the Master Supply Agreement will take precedence and apply.

#### **2. Delivery Terms**

2.1 Delivery Date is to be understood as the time the Products must be available at the Delivery Location indicated on the Purchase Order in accordance with the agreed (INCOTERMS 2000). Manufacturer commits to a Delivery Date of no later than twelve weeks (absent specific agreement to the contrary) from the date of issuance of this Purchase Order, failing which the Procurement Agent reserves the right to amend or cancel the order and CHAI reserves the right to cancel the Agreement.

2.2 Manufacturer commits to submitting the following documents/information to the consignee by email or fax at least two (2) days before arrival of Products: (i) ship or flight details, (ii) Bill of Lading or Air Way Bill, (iii) pro forma Manufacturer's invoice, (iv) packing list, and (v) a Certificate of Analysis ("COA") for each batch manufactured under this Purchase Order (the COA, together with the items listed in (ii)-(v) above, each a "Document" and, together, the "Documents"). One of each of the documents will be attached to the consignment and one of each of the Documents will be placed inside shipping carton number 1 unless specified otherwise in the packing list due to particular packing needs.). Where a country requires that the invoice be certified by Chambers of Commerce in the Manufacturer's country, the Manufacturer shall submit such 'chamberised' Invoices as part the shipping documents.

2.3 Manufacturer will submit to CHAI within 5 days of the arrival of the Product a proof of delivery to the delivery location indicated on the Purchase Order. CHAI through the Procurement Agent will also arrange for confirmation of the receipt of the products by the beneficiary country to be sent to CHAI by means of a written acknowledgement from the Country of its designee (the "Arrival Report").

### **3. Payment Terms**

3.1 On fulfillment of the Purchase Order and the delivery terms noted in Section 2 above, unless otherwise specified in the Purchase Order, payment shall be made within 45 days of receipt of the Products and the proper submission of the Documents by the Manufacturer and confirmation of delivery to the agreed destination in the Beneficiary Country (“Delivery Location”) by means of an arrival report provided to CHAI. All prices should be stated FCA Airport. The specified Incoterm (and related geographical location), as well as the identification of the Delivery Location would be designated by Procurement Agent and inserted into the individual Purchase Order. Manufacturer shall indicate the value of goods and components of Other Charges, such as Freight and Insurance, separately in each invoice. Manufacturer shall submit to CHAI actual bills from its freight forwarders and other freight and logistics vendors towards such Other Charges within 45 days of the Delivery of goods.

3.2 The prices for the products secured in the Master Supply Agreement are expected to remain ceiling prices for the duration of the Agreement.

3.3 Inspection by the Procurement Agent or its designated agent prior to shipment does not relieve the Manufacturer from its contractual obligations.

3.4 The Procurement Agent shall have a reasonable time after receipt of goods at the final location in the destination country (as specified by the Procurement Agent in its purchase order) of the Products to inspect them and to reject and refuse acceptance of Products not conforming to the Purchase Order. Acceptance of Products shall follow inspection and confirmation that the Products delivered meet the Terms and Conditions of the Purchase Order. Payment for Products pursuant to the Purchase Order shall not be deemed acceptance of the Products.

3.5 If, after inspection, the Products are not found to be conforming to the Purchase Order, the Procurement Agent shall reject such Products and shall (i) promptly contact Manufacturer regarding the non-conforming Products and (ii) negotiate for reimbursement of the cost of such Products. The Procurement Agent specifically reserves the right to deduct the payment made for such non-conforming Products and any costs incurred in connection with the replacement of such non-conforming Products from future payments due to Manufacturer.

### **4. Quality Assurance**

4.1 All Products are required to be in compliance with national regulatory standards of the respective beneficiary country, prequalified by WHO or other stringent national regulatory authority, which includes compliance with standards for good manufacturing practices (“GMP”) or approved for supply as the outcome of an ERP assessment.

4.2 All products must conform to the quality assurance standard as set forth in Schedule 6 of the Manufacturer Letter.

### **5. Tax Exemption**

To the extent that UNITAID or CHAI is exempt from all direct taxes and is exempt from customs duties in respect of articles imported or exported for its official use, then accordingly, the Manufacturer authorizes the Procurement Agent, acting on behalf of UNITAID, to deduct from the Manufacturer's invoice any amount representing such taxes or duties charged by the Manufacturer to Procurement Agent. Payment of such corrected invoiced amount shall constitute full payment by Procurement Agent. In the event any taxing authority refuses to recognize the exemption status from such taxes, the Manufacturer shall immediately consult with the Procurement Agent to determine a mutually acceptable procedure for allocation of

responsibility for payment of taxes. Manufacturer shall pay all taxes under this Section 5 when due, subject to reimbursement by the Procurement Agent, in the event that UNITAID or CHAI is found to be responsible for these taxes.

## **6. Export License**

The contract is subject to the obtaining of any export license or other governmental authorization which may be necessary. It will be the responsibility of the Manufacturer to obtain such license or authorization, but CHAI will provide reasonable assistance upon request.

## **7. Risk of Loss, Terms of Shipment**

All risk of loss, delay or damage in transit to the Products, as well as the cost of freight and insurance shall be borne by the Manufacturer until physical delivery to the Delivery Location.

## **8. Intellectual Property Warranties**

Manufacturer warrants that the use or supply by CHAI, UNITAID, WHO or the Beneficiary Countries of the Products offered for sale under the Purchase Order do not infringe any patent, design, trade-name, or trade-mark. In addition, the Manufacturer shall, pursuant to this warranty, indemnify, defend and hold harmless CHAI and WHO/UNITAID, donors of resources being used to finance the Products from and against all claims, damages, losses, costs and expenses arising out of the alleged infringement of a patent, design, trade-name or trade-mark arising under or relating to the Purchase Order. CHAI shall promptly give notice to the Manufacturer of any such claims, damages, losses and costs and expenses and shall in such event cooperate in a reasonable manner with the Manufacturer.

## **9. Force Majeure**

Force majeure as used in this Section 9 means acts of God, war (whether declared or not), invasion, revolution, insurrection, or other acts of a similar nature or force. In the event of and as soon as possible after the occurrence of any cause constituting force majeure, the affected Party shall give notice and full particulars in writing to the other Party, of such occurrence if that Party is thereby rendered unable, wholly or in material part, to perform its obligations and meet its responsibilities under this Purchase Order and that Party shall be relieved of these obligations and responsibilities for so long as such circumstances prevail. If a Party is rendered permanently unable, wholly, or in material part, by reason of force majeure to perform its obligations and meet its responsibilities under this Purchase Order, the other Party shall have the right to suspend or terminate this Purchase Order on the same terms and conditions as are provided for in the Master Supply Agreement.

## **10. Rights of Procurement Agent**

In case of failure by the Manufacturer to perform under the Terms and Conditions of the Purchase Order, including but not limited to failure to obtain necessary export licenses, or to make delivery of all or part of the Products by the agreed delivery date or dates, Procurement Agent may, after giving the Manufacturer reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights (i) procure all or part of the Products from other sources, in which event Procurement Agent may hold the Manufacturer responsible for any excess cost occasioned thereby; (ii) refuse to accept delivery of all or part of the Products; and/or (iii) terminate the Purchase Order.

## **11. Product Warranty**

11.1 Manufacturer warrants that the Products, as of the date of delivery: (i) comply with all laws, rules and regulations applicable to such Product; (ii) have been handled and processed so as not to be contaminated, adulterated, changed or rendered unsafe or unfit for its intended use; and (iii) are free and clear of any lien or encumbrance.

11.2 Manufacturer warrants that the Products, including adequate packaging, conform to the formula, specifications and standards as approved by, or as submitted to for approval by, the WHO and/or a stringent regulatory authority and are of merchantable quality and fit for the purposes for which such Products are ordinarily used and for purposes expressly made known to the Manufacturer by CHAI, and are free from defects in workmanship and materials. The Manufacturer also warrants that the Products are contained or packaged adequately to protect the Products.

11.3 Manufacturer shall bear sole responsibility for the validity of all test methods and appropriateness of all Product specifications. In addition, Manufacturer shall bear sole responsibility for all regulatory approvals, filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies. Manufacturer further warrants that it shall obtain any and all necessary approvals from the appropriate National Drug Regulatory Authority (“NDRA”) to distribute and sell all Products under a specific Purchase Order. Manufacturer warrants that it shall obtain any and all necessary approvals from the WHO or US FDA or stringent regulatory authority, for products as set forth in the applicable Purchase Order. If the Manufacturer is unable to obtain the necessary approval(s) as stated above, the Manufacturer shall have the option to reject the Purchase Order.

11.4 Manufacturer and CHAI shall co-operate to identify the applicable regulatory approvals required for Products under a specific Purchase Order or under anticipated Purchase Orders in accordance with the Master Supply Agreement.

11.5 Subject to the provisions set forth in the Master Supply Agreement, Manufacturer warrants that all Products manufactured, held for sale, sold and shipped pursuant to this Agreement shall have been manufactured and shipped by Manufacturer in substantial compliance with the United States Food, Drug and Cosmetic Act of 1938 (21 U.S.C. Section 201 et seq.) together with any regulations promulgated thereunder, including, without limitation, all Good Manufacturing Practices, in each case as amended from time to time.

11.6 Manufacturer warrants that all product design, labeling copy and artwork approved, designated or supplied by Manufacturer shall be in compliance with all Applicable Laws and governmental regulations and that such compliance is the sole responsibility of Manufacturer. Manufacturer hereby represents and warrants to the Procurement Agent that none of the formulas, components and artwork related to the Product violate or infringe any patent, copyright, trademark or other intellectual property right of any third Party in Manufacturer’s country or the destination country of the Product. Manufacturer shall notify the Procurement Agent of any patent or other intellectual property infringement claim against Manufacturer, relevant to the applicable Purchase Order at the time of acknowledgement of the Purchase Order and Procurement Agent shall have the option to proceed or cancel the Purchase Order at that time.

11.7 The Manufacturer warrants that the use or supply by Procurement Agent of the Products offered for sale under the Purchase Order does not infringe any patent, design, trade-name, or trade-mark.

11.8 Manufacturer shall be responsible for the costs and expense of any product recall resulting from Manufacturer’s supply of defective products, and shall refund to Procurement Agent any payment for such Products.

## **12. Indemnity**

12.1 Manufacturer agrees to indemnify, defend and hold the Procurement Agent, CHAI and WHO/UNITAID harmless from and against any claims, losses, liability, obligations, lawsuits, deficiencies, damages or expense of whatever nature, whether known or unknown, accrued, absolute, contingent or otherwise, including, without limitation, interest, penalties, reasonable attorney's fees, costs of investigation and all amounts paid in defense or settlement of the foregoing (collectively, "Loss"), suffered or incurred by the Procurement Agent as a result of the occurrence of, or arising out of, any breach of this Agreement by Manufacturer, including, but not limited to, any of Manufacturer's representations and warranties contained herein.

12.2 Manufacturer also agrees to indemnify, defend and hold the Procurement Agent, CHAI and WHO/UNITAID harmless from and against any Loss suffered or incurred by the Procurement Agent, CHAI and WHO/UNITAID arising out of or relating to: (i) any third Party product liability claim against any Product; (ii) any defects in any Product supplied; or (iii) any non-compliance by such manufacturer or Manufacturer with any technical requirements applicable to any Products supplied.

12.3 Manufacturer also agrees to indemnify, defend and hold the Procurement Agent, CHAI and WHO/UNITAID from and against all claims, damages, losses, costs and expenses arising out of the alleged infringement of a patent, design, trade-name or trade-mark arising under or relating to the Agreement.

12.4 Procurement Agent agrees to give prompt notice to the Manufacturer (the "Indemnitor") of any third-Party claim, action, suit, complaint or proceeding that might give rise to a claim based on the indemnity contained in this Section 12, stating the nature and basis of the claim and the amount thereof; provided, that no delay on the part of the Procurement Agent in giving any such notice shall relieve Indemnitor of any indemnification obligation hereunder unless, and then solely to the extent that, Indemnitor is materially prejudiced by such delay. Further, the Procurement Agent shall tender the defense of such claim to Indemnitor and the Procurement Agent shall provide reasonable assistance to Indemnitor in the defense of such claim.

## **13. Use of Name, Emblem or Official Seal of CHAI or WHO/UNITAID**

The Manufacturer shall not, without prior written consent from CHAI, and/or WHO/UNITAID, as appropriate, advertise or otherwise make public the fact that it is a Manufacturer or in any other way affiliated with CHAI, WHO/UNITAID, President Clinton or the Projects, nor shall the Manufacturer, in any manner whatsoever use the name, emblem or official seal of CHAI, UNITAID, WHO, President Clinton, or any abbreviation of the name of CHAI, UNITAID, WHO and/or President Clinton in connection with its business or other activities. Any proposed public written reference to the relationship of the Parties or to UNITAID in connection with the Projects or to President Clinton (including his name, image, voice or likeness) will be agreed in writing in advance.

## **14. Liability Insurance**

Manufacturer shall obtain or maintain adequate liability insurance covering the claims and liabilities referred to in Sections 8, 11 and 12 above.

## **15. Assignment and Insolvency**

15.1 The Manufacturer shall not assign, transfer, pledge or make other disposition of this contract or any part thereof, or any of the Manufacturer's rights, claims or obligations under the Purchase Order except with the prior written consent of CHAI.

15.2 Should the Manufacturer be adjudged bankrupt, or be liquidated or become insolvent, or should the Manufacturer make an assignment for the benefit of its creditors, or should a Receiver be appointed on account of the insolvency of the Manufacturer, Procurement Agent may, without prejudice to any other right or remedy it may have under the terms of these conditions terminate this Purchase Order forthwith. The Manufacturer shall immediately inform the Procurement Agent and CHAI of the occurrence of any of the above-events.

#### **16. Arbitration**

Any dispute, controversy or claim arising out of or relating to this Agreement, including any question regarding this Agreement's existence, validity or termination or any breach of the same shall be settled by final and binding arbitration. Any arbitration pursuant to this provision shall be administered by the American Arbitration Association in accordance with its International Arbitration Rules. The place of arbitration shall be New York, New York. The language of the arbitration shall be English. The number of arbitrators shall be one, to be nominated jointly by the parties. If one arbitrator cannot be agreed upon by the parties within thirty (30) days of the notice of arbitration, then the arbitrator shall be appointed by the administrator of the American Arbitration Association. The parties shall bear their own attorneys', experts' and other fees and expenses in connection with any arbitration unless otherwise determined by the arbitrator. Any laws allowing or providing for a judicial review de novo of such arbitration are hereby waived, and the award of the arbitrator shall be final, binding and not subject to de novo review.

#### **17. Privileges and Immunities of WHO/UNITAID**

Nothing in or relating to the Contract shall be deemed a waiver of any of the privileges and immunities enjoyed by WHO or UNITAID under national or international law, convention or agreement, or submit WHO or UNITAID to any national court jurisdiction. Similarly, nothing contained herein shall be construed as conferring any responsibility or liability upon WHO or UNITAID in relation to or as a result of the supply of the products under this Purchase Order.

#### **18. Request for Price Adjustment**

The prices for the products are expected to remain ceiling prices for the life of the MSA, or at least until February 28, 2012, whichever date is later. Exceptionally, should a significant and sustained change in circumstances create a need for an upward price adjustment, such adjustment shall be subject to the advance written approval of UNITAID. Such a request must be submitted to UNITAID, through CHAI, at least one month prior to the requested effective date, together with documentary proof of the circumstances that are claimed to warrant a price adjustment. While the request is under consideration by UNITAID and CHAI, the Manufacturer will continue to supply the product without interruption at the originally agreed upon price in the Purchase Order. No retroactive price increases will be permitted for purchase orders already issued to and accepted by the Manufacturer.

#### **19. Manufacturer Performance**

Supplier will be evaluated based on its performance of obligations under the terms and conditions set forth in the Master Supply Agreement.

UNITAID and CHAI, jointly and severally, reserve the right to share, publish, disseminate or otherwise make public any information on supplier performance under the two Projects. This right shall extend, but shall not be limited, to any metrics on supply performance; ranking of

suppliers by product, category or geography; lead times or any time based delivery metrics; among others. UNITAID and CHAI further reserve the right to make this information public either during the period covered by the MSAs signed in pursuance to this letter or after any such period.

## 20. Labeling

20.1 The Projects, which are the subject of the Master Supply Agreement, shall be referred to, respectively, as the "UNITAID-CHAI Pediatrics HIV/AIDS Project 2011" and the "UNITAID-CHAI Second-line HIV/AIDS Project 2011".

20.2 All documents issued by the Manufacturer in connection with the supply or delivery of UNITAID-funded products or services (including but not limited to agreements with local providers) should clearly indicate they were funded by UNITAID.

20.3 Manufacturer will ensure that the packaging of products shall bear a label and/or text to indicate they were funded by UNITAID (e.g., in the form of a sticker).

20.4 The shipping and other related documents for the Drugs shall be marked "*For UNITAID-funded Project: Free of Charge- Not for Sale,*" and shall state the name of the party to whom the Drugs are to be delivered, the Purchase Order number, and the Destination. This is to prevent, or aid in the prevention of, the Drugs being diverted from their intended recipient and use under the Project.

## 21. Publication of Prices

It is understood that UNITAID regularly reports to the public the prices paid by UNITAID for products procured with UNITAID support, including those agreed by CHAI with Manufacturers. The Manufacturer authorizes UNITAID to publicly disclose the prices for the products procured in relation to the Project as well as the name of the Manufacturer in question.

## 22. Reporting of Ex Works Prices

If the purchase price differs from the ex-works price, during the submission of price bids, the Manufacturer will provide to CHAI a written report of the price charged for each product supplied in the project on an ex-works price basis for purposes of monitoring and market analysis.

## **SCHEDULE 6**

### **Summary of Applicable UNITAID Quality Assurance Standard for Drugs Procured in Pediatric and Second Line ARV Projects**

All drugs procured under the UNITAID-funded Pediatric or Second-line ARV Projects are required to be in compliance with national regulatory standards and prequalified by WHO or other stringent national regulatory authority,<sup>4</sup> which includes compliance with standards for good manufacturing practices (“GMP”).

In the case of single or limited-source pharmaceuticals, (a) the drugs must be either prequalified by WHO or approved by a stringent regulatory authority or (b) in case there is only one or no equivalent product that meets this condition, proof that an application for assessment together with a complete dossier for the product must have been submitted to and accepted by the WHO or another stringent regulatory authority and the product must be manufactured at a site that is compliant with WHO or stringent regulatory authority standards of GMP, provided that the Ministry of Health of the beneficiary country concurs that the products may be supplied on the basis of the conditions set out in (b).

Furthermore, where a product falls into category (b), it must be reviewed for quality, efficacy and safety and receive an interim recommendation for procurement for a period not exceeding 12 months, based on advice provided by the Expert Review Panel (ERP) as convened by UNITAID or The Global Fund, before procurement can begin. If the product does not meet the applicable quality criteria, the product will not be supplied with UNITAID funds.

The technical assessment referenced in the preceding paragraph may include a quality risk assessment conducted by the WHO Prequalification Programme, at the request of UNITAID. The assessment shall be performed in accordance with such procedures as are determined by the WHO Prequalification Programme. The approval is expected to be of limited duration, but not more than 12 months.

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<sup>4</sup> With reference to approval by a stringent national regulatory authority, it should be noted that all Products need to be (i) manufactured at a site located in a highly regulated country defined as an ICH member country, ICH observers and any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement or at a site approved by a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S) (ii) approved for safety, quality and efficacy by a regulatory authority of an ICH member country, ICH observer country or any country whose regulatory authority is associated with an ICH member through a legally binding mutual recognition agreement or subject to a positive opinion under the Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC) No. 726/2004 or United States FDA tentative approval. (For ICH members, observers or associated countries, see [www.ich.org](http://www.ich.org). For PIC/S, refer to [www.picscheme.org](http://www.picscheme.org)).

# **SCHEDULE 7**

## **Quality Control Requirements**

CHAI is responsible for ensuring proper quality assurance (“QA”) and quality control (“QC”) testing of products procured for the UNITAID Pediatric and Second-Line Projects. Testing and pre-shipment inspection will be performed by a testing agency (“TA”) specified by CHAI. The selection of TA and its qualifications shall be agreed with UNITAID. CHAI will be responsible for costs incurred by the testing agency. For QC testing the TA will randomly select 20% of batches of prequalified products and 40% of batches of non-prequalified products. The tests to be performed should include: appearance, identity, assay, related substances, mass uniformity and dissolution, unless justified otherwise.

### **Pharmacopoeial Monographs and Test Methods**

Testing will be performed against an Acceptable Monograph, if available. An “Acceptable Monograph” is one that has: (i) been published in the US Pharmacopoeia or International Pharmacopoeia or (ii) has been published to the web sites of the US Pharmacopoeia or International Pharmacopoeia. In addition, testing against monographs published in other pharmacopoeia may be permitted by CHAI on a case by case basis.

Testing in the absence of a published monograph may be based on published methods, methods developed by the TA, or Manufacturer developed methods. Manufacturer methods should be validated according to ICH guidelines and the Manufacturer is responsible for providing a validation report. Further, the Manufacturer is expected to support method transfer by providing relevant samples and necessary technical assistance to the TA. If a method is subsequently published by the US pharmacopoeia or the International Pharma, the Manufacturer shall changes its testing methods to use the pharmacopoeial method this method within 120 days. CHAI will be responsible for final decisions regarding selection of test methods.

### **Samples and Working Standards**

The Manufacturer is required to provide the following, at no extra charge, for every Batch (in case of Laboratory testing) and for every Shipment (in case of Pre-shipment Inspection), in order to enable proper testing:

- a) Samples for Laboratory Testing
- b) Samples for Pre-shipment Inspection
- c) Placeboes sufficient to test one batch.

The TA is responsible for maintaining reference materials required to perform testing. Primary standards may be obtained from pharmacopoeial organizations and used to establish working standards. Materials for working standards may be requested from Manufacturers and may be used for multiple batches. Crude samples of API with characterized levels of critical impurities may be used to quantify impurity levels in place of primary standards of these impurities. Such samples may be obtained from the Manufacturer and may be used for multiple batches.

### **Retain Samples**

The Manufacturer is obliged to collect and maintain retain samples of Finished Dose Formulation (FDF) and API of every batch produced according to a Standard Operating

Procedure (SOP) addressing such samples. The Manufacturer is required to provide a copy of this SOP.

### **Certificates of Analysis**

The Manufacturer is responsible to supply Certificates of Analysis and packing lists of every batch to be supplied for the UNITAID Pediatric and Second-Line Projects. Manufacturer shall not ship the stocks unless Clean Report of Findings is received from the TA when a Pre-shipment Inspection has been conducted for the shipment.

CHAI reserves the right to test/ inspect every batch/ shipment.

### **PIC/s Audit reports**

Manufacturers are required to provide copies of PIC/S (or FDA) audit reports from the past 2 years:

- a. Copies of audit reports from the US FDA, UK-MHRA or WHO Geneva, if these agencies have audited the API and formulations manufacturing facilities in the last 2 years
- b. Copies of all PIC/S reports for the API and formulations manufacturing facilities in the last two years, if the US FDA, UK-MHRA or WHO Geneva have not audited the facility in the past 2 years

While existing audit reports may obviate the need for on-site inspection CHAI reserves the right to call for such an inspection. Examples of situations in which CHAI may conduct an audit include, but are not limited to, the following: after a PIC/S agency identifies problems in the facility, and/or if a limited number of PIC/S audits have occurred in the past 2 years.

### **Product Recall**

Manufacturers will be responsible for communicating, conducting, and paying for any product recalls that may be required. Manufacturers are required to provide a copy of their Standard Operating Procedure (SOP) to be followed in case of a product recall.

## SCHEDULE 8

### **Mutual Non-Disclosure Agreement**

THIS MUTUAL NONDISCLOSURE AGREEMENT (this "**Agreement**") is made as of the date written below by and between the Clinton Health Access Initiative ("**CHAI**"), an Arkansas nonprofit corporation, and \_\_\_\_\_ ("**Manufacturer**"), a corporation organized under the laws of \_\_\_\_\_.

**WHEREAS**, the parties are interested in discussing terms and conditions for the sale of raw materials, chemical intermediates, active pharmaceutical ingredients and/or finished pharmaceutical products (collectively, "**Products**") for the treatment of HIV/AIDS in developing countries; and

**WHEREAS**, in connection with these discussions each party may disclose to the other certain proprietary and confidential information with respect to manufacture of Products, including manufacturing processes and techniques, sources of supply, regulatory documentation and cost data, for the purposes of furthering CHAI's goal of lowering production costs of high-quality Products for treatment of HIV/AIDS working together to further that goal, and permitting each to evaluate its interest in entering into one or more agreements governing the supply of Products (the "**Purpose**"); and

**WHEREAS**, neither party is willing to proceed with these discussions unless they have an agreement governing the disclosure of this confidential information and restricting further disclosure thereof,

**THEREFORE**, in reliance upon and in consideration of the above and the following undertakings, the parties agree as follows:

1. "**Confidential Information**" means (a) any information relating to the Product disclosed by either party to the other party, either directly or indirectly, in writing or orally, including, without limitation, business plans, data, lists, names, designs documents, drawings, financial analysis, forecasts, formulas, know-how, ideas, inventions, market information, marketing plans, processes, products, product plans, research, specifications, software, source code, trade secrets or any other information which is designated as "confidential," "proprietary" or some similar designation (collectively, the "**Disclosed Materials**") and (b) any information related to the Product otherwise obtained, directly or indirectly, by a receiving party through inspection, review or analysis of the Disclosed Materials. Confidential Information may also include information of a third party that is in the possession of one of the parties and is disclosed to the other party under this Agreement. Confidential Information shall not, however, include any information that (i) was publicly known and made generally available in the public domain prior to the time of disclosure by the disclosing party; (ii) becomes publicly known and made generally available after disclosure by the disclosing party to the receiving party through no action or inaction of the receiving party; (iii) is already in the possession of the receiving party at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately prior to the time of disclosure; (iv) is obtained by the receiving party from a third party lawfully in possession of such information and without a breach of such third party's obligations of confidentiality; or (v) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as shown by documents and other competent evidence in the receiving party's possession.

2. *Non-use and Non-disclosure.* Each party agrees to use the Confidential Information disclosed to it by the other only to the extent required to accomplish the Purpose. Without the prior written consent of the other party, neither party will disclose to any other person the fact that the Confidential Information has been made available, that discussions or negotiations are taking place concerning a

possible transaction involving the parties, or any of the terms, conditions or other facts related to such discussions or negotiations, including the status thereof. Each party agrees not to disclose any Confidential Information of the other party, except that, subject to Section 3 below, a receiving party may disclose the other party's Confidential Information to those employees, consultants and affiliates of the receiving party who are required to have the information in order to evaluate or engage in discussions concerning the Purpose. If a receiving party is required by law to make any disclosure that is prohibited or otherwise constrained by this Agreement, the receiving party will provide the disclosing party with prompt written notice of such requirement so that the disclosing party may seek a protective order or other appropriate relief. Subject to the foregoing sentence, such receiving party may furnish that portion (and only that portion) of the Confidential Information that the receiving party is legally compelled or is otherwise legally required to disclose; provided, however, that the receiving party provides such assistance as the disclosing party may reasonably request in obtaining such order or other relief.

3. *Maintenance of Confidentiality.* Each party agrees that it shall take reasonable measures to protect the secrecy of and avoid disclosure and unauthorized use of the Confidential Information of the other party. Without limiting the foregoing, each party shall take at least those measures that it takes to protect its own confidential information of a similar nature, but in no case less than reasonable care (including, without limitation, all precautions the receiving party employs with respect to its confidential materials). Each party shall ensure that its employees, consultants and affiliates who have access to the other party's Confidential Information have signed a non-use and non-disclosure agreement in content similar to the provisions of this Agreement or are otherwise legally obligated not to disclose such Confidential Information, prior to any disclosure of Confidential Information to such persons. Each party shall reproduce the other party's proprietary rights notices on any such authorized copies, in the same manner in which such notices were set forth in or on the original. A party receiving Confidential Information shall promptly notify the party disclosing such Confidential Information of any use or disclosure of such Confidential Information in violation of this Agreement of which the receiving party becomes aware.

4. *No Obligation.* Nothing in this Agreement shall obligate either party to proceed with any transaction between them, and each party reserves the right, in its sole discretion, to terminate the discussions contemplated by this Agreement concerning the Purpose.

5. *Return of Materials.* All documents and other tangible objects containing or representing Confidential Information that have been disclosed by either party to the other party, and all copies or extracts thereof that are in the possession of the other party, shall be and remain the property of the disclosing party and shall be promptly returned to the disclosing party upon the disclosing party's written request. Notwithstanding the foregoing, a receiving party may retain in the offices of its legal advisor a single archival copy of any written or photographic Confidential Information provided by the other party under this Agreement, which copy shall only be used by the receiving party and its legal advisors in connection with the review of its obligations under this Agreement.

6. *No License.* Nothing in this Agreement is intended to grant any rights to either party under any patent, trademark, copyright, trade secret or other intellectual property right of the other party, nor shall this Agreement grant any party any rights in or to the other party's Confidential Information.

7. *Foundation Marks.* The parties acknowledge the Foundation's ownership of the William J. Clinton Foundation name and logos, the names and logos of the Foundation's programs and initiatives and, as President Clinton's representative, the name, voice, likeness and images of President Clinton, in any format (collectively, the "**Foundation Marks**"). This Agreement shall not be construed to grant any license to use the Foundation Marks without the prior written consent of the Foundation. Any and all requests for use of the Foundation Marks, expressly including images or quotes of President Clinton, shall be submitted to the Foundation and will require its prior written approval prior to any such use.

8. *Term.* Unless earlier terminated by written notice of one party to the other, the obligations of each party under this Agreement shall survive for a period of twenty-four (24) months from the date hereof, after which time the rights of the receiving party to access and use the Confidential Information for the purposes permitted pursuant to this Agreement shall terminate, unless otherwise agreed by the parties. Upon termination of this Agreement at any time, all Confidential Information shall upon request

be returned to the other party in accordance with Section 6 above. The obligation with respect to non-disclosure of Confidential Information shall survive the termination of this Agreement.

9. *Availability of Equitable Relief.* Each party understands and agrees that its breach or threatened breach of this Agreement will cause irreparable injury to the other party and that money damages will not provide a sufficient remedy for such breach or threatened breach, and both parties hereby agree that, in the event of such a breach or threatened breach, the non-breaching party will also be entitled, without the requirement of posting a bond or other security, to equitable relief, including injunctive relief and specific performance. The parties' rights under this Agreement are cumulative, and a party's exercise of one right shall not waive the party's right to assert any other legal remedy.

10. *Counterparts and Facsimiles.* The parties may execute this Agreement in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement. This Agreement may be delivered by facsimile transmission, and facsimile copies of executed signature pages shall be binding as originals.

11. *Interpretation and Enforcement.* This Agreement shall be interpreted and enforced in accordance with the laws and by the courts of the State of New York, without regard to principles of choice of laws. The invalidity of any provision of this Agreement shall not affect the remainder of that provision or any other provision of this Agreement.

12. *Miscellaneous.* This Agreement shall benefit and bind the parties and their respective successors, heirs, legal representatives and permitted assigns. This Agreement constitutes the entire agreement between the parties with respect to the Purpose and supersedes all prior written and oral agreements between the parties regarding the subject matter of this Agreement, and neither party shall have any obligation, express or implied by law, with respect to trade secret or proprietary information of the other party except as set forth in this Agreement. No provision of this Agreement may be waived except by a writing executed by the party against whom the waiver is to be effective. A party's failure to enforce any provision of this Agreement shall neither be construed as a waiver of the provision nor prevent the party from enforcing any other provision of this Agreement. No provision of this Agreement may be amended or otherwise modified except by a writing signed by the parties to this Agreement.

13. *Notice.* All notices and requests in connection with this Agreement shall be given to the parties via certified mail, return receipt requested, by recognized overnight delivery service, by facsimile, or by hand, at the addresses listed on the first page of this Agreement, or at such other addresses (including e-mail) as set forth below. All notices and requests shall be deemed given the earlier of seven (7) days after duly deposited in the mails properly addressed with postage prepaid, or when actually received.

[NAME]	Clinton Health Access Initiative
Name:	Randal Walther
Title:	Acting Chief Financial Officer Clinton Health Access Initiative
Address:	383 Dorchester Avenue, Suite 400 Boston, MA 02127
Phone:	617-774-0110
Fax:	617-774-0220
Email:	<a href="mailto:rwalther@clintonhealthaccess.org">rwalther@clintonhealthaccess.org</a>

[Signatures appear below]

ACKNOWLEDGED and AGREED to  
this \_\_\_\_ day of \_\_\_\_\_, 200\_

[ORGANIZATION]

By: \_\_\_\_\_

Name:

Title:

By: \_\_\_\_\_

Randal Walther

Acting Chief Financial Officer

Clinton Health Access Initiative

## **SCHEDULE 9**

### **Description of Cost-Plus Informational Requirements**

For manufacturers electing to pursue cost-plus negotiations, the following information is required:

#### **A. Required cost-of-production data for formulations:**

For *each formulation*, required information includes:

- number of packs/year
- total manufacturing costs
- the price of API from each source
- names and locations of each source and alternate source of API
- API losses (on a percentage basis) during formulation manufacture
- total cost of excipients, and any individual component totaling more than 5% of total formulation cost
- total cost of packing materials, and any individual component totaling more than 5% of total formulation cost
- cost of each overhead category, as described in the attached formulation cost-plus worksheet

These requirements are also described in the attached formulation cost-plus worksheet.

#### **B. Required cost-of-production data for manufacturers that manufacture the associated API used in these formulations:**

Manufacturers that manufacture the associated API used in the formulations are required to provide detailed cost-of-production information for the following APIs: tenofovir, efavirenz, lopinavir, ritonavir,, atazanavir, and zidovudine. Information required for tenofovir, efavirenz, lopinavir, ritonavir,, atazanavir includes the following (zidovudine requirements are fewer and described below):

- total API cost;
- total raw material costs;
- costs and utilization factor of each key raw material contributing 10% or more to total raw material cost;
- direct manufacturing costs;
- indirect manufacturing costs; and
- any other costs contributing 5 % of more to the total API cost.

Additionally, manufacturers must submit a process map with step-wise yields (an example is provided in worksheet).

Manufacturers that manufacture the associated Zidovudine API in the formulations listed in category P4 (in section D of Schedule 2) are required to provide the following information:

- approved sources and prices of beta-thymidine
- total manufactured cost of the AZT API.

These requirements are also described in the attached API cost-plus worksheet.

